acurable

AcuPebble Ox200

User Manual

(Instructions for Use and Technical Information)

Table of contents / Index

Document control

Document name	User Manual
Document reference	ACU-IFU-OX-US-200
Document version	1.4.1
Issue date	2025-03-26
Document classification	Customer Confidential
Status	Issued

Device version

DEVICE COMPONENT	VERSION
AcuPebble sensor	100
OxiPebble sensor	100
AcuPebble/OxiPebble adhesives	1.0
AcuPebble mobile application	2.4 (iOS), 2.4 (Android)
AcuPebble web application	2.5
AcuPebble Ox200 algorithms	1.0

Glossary

TERM	DEFINITION
A/D	Analog-to-Digital
AASM	American Academy of Sleep Medicine
ACU	Acurable
AcuPebble_AHI	Apnea-Hypopnea Index calculated only using acoustic signal
AcuPebble_ODI	Oxygen Desaturation Index calculated only using acoustic signal
BLE	Bluetooth Low Energy
bpm	beats per minute (cardiac)
CE	Administrative marking which indicates that a product may be sold freely in any part of the European Economic Area
CI	Confidence Interval
CISPR	Comité International Spécial des Perturbations Radio
dBm	Decibel-Milliwatts
DC	Direct Current
e.i.r.p.	Effective Isotropic Radiated Power
EEG	Electroencephalogram
EMC	Electromagnetic Compatibility
ES6	ECMAScript 6
GHz	Gigahertz
GFSK	Gaussian frequency shift keying
HCP	Healthcare Professional

TERM	DEFINITION
HF	High Frequency
IFU	Instructions for Use
IP	Ingress Protection
ISM	Industrial, Scientific and Medical
kPa	Kilopascal
Li-Po	Lithium Polymer
LoA	Limits of Agreement
mA	Milliampere
mAh	Milliamp Hour
MHz	Megahertz
OSA	Obstructive Sleep Apnea
PPG	Photoplethysmogram
QR	Quick Response code
RF	Radio Frequency
SA	Sleep Apnea
UK	United Kingdom
US	United States
μ	Bias
σ	Standard deviation

1. Introduction

Thank you for purchasing this product. Before using it, please read this user manual carefully. We would be grateful for any feedback and/or suggestions you have on this product, to help us improve it in the future.

The sensors MUST be used with the adhesive provided by Acurable Ltd. The performance of the system largely depends on this specific adhesive and hence cannot be guaranteed if an alternative one is used.

The device is not guaranteed if the enclosure is opened. Trying to repair it or modify it will void the guarantee.

Acurable Ltd., 20 Victoria Street, London SW1H 0NB, United Kingdom

Acurable Ltd., 2 Leman Street, London E1W 9US, United Kingdom

2. About this user manual

It is very important that you read each paragraph that you see with this icon, since it is used in the following sections to indicate potential danger. This danger could be to the patient, property, data, or connection with other devices. This user manual is part of this medical device and it must be kept available.

Acurable does not consider itself responsible for the effect on basic safety, reliability and performance of the system if:

· The system has been modified in any way or form.
· The system has been used outside the remit and/or operating conditions specified in this user manual.
· The system has not been used in accordance with this user manual.

This user manual is only intended to be used by healthcare professionals with the relevant clinical training as determined by the responsible healthcare organisation.

2.1 Explanation of symbols used

This warning symbol is used to represent potential danger to patients, property or data loss.

This symbol is used to indicate paragraphs that are essential to read, since they make reference to potential danger.

This system complies with the IEC 60529, with an IP Rating of at least "22". This means that it is protected against insertion of fingers and will not be damaged or become unsafe during a specified test in which it is exposed to vertically or nearly vertically dripping water.

This device works with a nominal 3.7 volts DC.

Protection class: Type BF applied part (device in contact with the patient).

HF transmitter with integrated Bluetooth Smart protocol.

This symbol represents a landline phone number is provided as contact method.

This symbol represents a mobile phone number is provided as contact method.

This symbol represents an email address is provided as contact method.

This symbol represents sections of this user manual that are self-contained in the mobile application, so the user can choose not to read them here, and follow the mobile application instead.

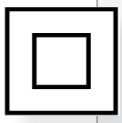
Never dispose of the system in domestic waste.

General prohibition sign.

Do not re-use.

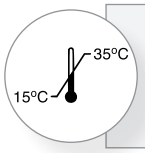
MD

This is a medical device.



This equipment meets the safety requirements specified for Class II equipment according to IEC 61140.

This device is not provided with a low SpO2 alarm condition.



Use in temperatures above 15°C (59°F) and below 35°C (95°F).

Acurable Ltd., 20 Victoria Street, London SW1H 0NB, United Kingdom

Acurable Ltd., 2 Leman Street, London E1W 9US, United Kingdom

FCC ID

A unique identifier assigned to a device registered with the United States Federal Communications Commission (FCC).

Rx Only

Federal Law (USA) restricts this system to sale by or on the order of a licensed healthcare practitioner.

3. Safety Warnings

This equipment needs to be installed and put into service in accordance with the information provided in this user manual.

Use only adhesive provided by Acurable Ltd. The performance of the system is linked to the properties of this adhesive. The system is not expected to work with any other.

Choking hazard. Keep away from small children.

No modification of this system is allowed.

If either enclosure is broken, dispose of the system.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Portable RF communications equipment should be used no closer than 30cm to any part of the equipment. Otherwise, degradation of the performance of this equipment could result.

This equipment has not been tested for safety in oxygen rich environments.

The sensors are not intended to be used continuously on the skin for more than 30 days.

Do not shower while wearing the system.

The micro-USB DC power port is solely intended for connection to a micro-USB charging device.

The device is not intended to be used as a real time apnea monitor. The Respiratory Rate should not be used to determine the presence of apneas. In the presence of movement artefacts, the claimed accuracy might be lower. Check the movement channel.

Do not use in subjects with a known allergy to acrylate.

Do not try to open the system enclosure.

Do not try to replace the battery.

Do not try to put on either of the sensors whilst charging the battery.

Do not use during an MRI examination.

Do not use with a defibrillator.

Do not re-use the adhesives once they have been pulled off the body, even if this is for an insignificant amount of time.

- The performance of this system has not been tested under extreme weather conditions. Hence, we recommend to use it indoors and in temperatures above 15°C (59°F) and below 35°C (95°F), humidity above 20% and below 75%, and atmospheric pressure above 70 kPa and below 106 kPa. For usage outside this temperature, humidity and atmospheric pressure range, please do contact Acurable Ltd.
- This system is at least IP22 in terms of water ingress. This means that it is protected against insertion of fingers and will not be damaged or become unsafe during a specified test in which it is exposed to vertically or nearly vertically dripping water. The system has however not been designed to be used under water, and should not be submerged in water or other liquids.
- Follow the manufacturer's instructions when cleaning the system.
- Once the seal is opened the system is non-returnable.
- The system contains Lithium batteries. These cannot be disposed of in domestic waste. Please return the system to your distributor or your local municipal collecting point when you wish to dispose of it.
- This system is not designed to be used in explosive environmental conditions.
- The lay operator or lay responsible organisation should contact Acurable or Acurable's representative:
    - For assistance in setting up, using or maintaining the system; or
    - To report unexpected operation or events.

4. About AcuPebble Ox200

4.1 Intended Use / Indications for Use

AcuPebble Ox200 is a wearable device intended for use in the recording, analysis, displaying, exporting, and storage of biophysical parameters to aid in the evaluation of adult patients with, or with suspected, obstructive sleep apnea (OSA). The device is primarily intended for home setting use (although it can also be used in healthcare settings) under the direction of a Healthcare Professional (HCP).

Figure 1: AcuPebble sensor (left and middle) and OxiPebble sensor (right)

4.2 Description of the Device

The AcuPebble Ox200 system is composed of two miniature electronic wireless multi-use wearable devices, one to be worn during sleep on the neck, and another one either on the !nger or on the forehead. Both of them attach to the body with a single use double coated medical tape. Both sensors are used to extract information during sleep about a variety of physiological processes/channels which are relevant for the diagnosis of obstructive sleep apnoea (OSA). In both cases, the sensors transmit signals to a mobile base station (i.e. mobile phone or tablet) and transmission occurs continuously. Transmission in both cases is carried out using a commercial Bluetooth Low Energy (BLE. 2.402-2.480 GHz frequency band, GFSK modulation and less than 4dBm radiated power) integrated circuit. They both operate with small Li-polymer batteries. In continuous operation, the system can function for over 20 hours (although note that for the intended purpose less than half of this is needed). The devices can be recharged using a standard micro-USB connector. The signals transmitted to the mobile phone can be uploaded to the Cloud, once the user stops the signal acquisition within the app, and there they are fully processed by algorithms that, amongst others, automatically determine diagnostic indexes. The outputs from both sensing devices are displayed in a Web app platform that can be accessed by physicians to aid the diagnosis.

The most cube-like sensor is, amongst others, used to measure peripheral oxygen saturation (SpO2). The principle of operation is as follows: light is shone into the tissue, part of which is absorbed. Photodiodes sense the light that is not and convert it into an electrical signal. Characteristics of the received infrared and red electrical signals are computed with electronic circuits. Using those measured characteristics, a scienti!cally well established algorithm based on what is known as the Beer Lambert law is used to calculate the SpO2 value.

The round neck sensor captures physiological body sounds and movements, having been designed to optimize the transmission of weak acoustic signals generated by the respiration and cardiac functions. From those signals algorithms are able to extract, amongst others, conventional obstructive sleep apnoea diagnostic indexes; from which the presence and severity of the disease can be obtained following the clinically worldwide established thresholds. The scientific rationale behind this is the well known scientific facts that respiratory, cardiac and movement sounds correlate with absence of breathing, obstructions, reductions in oxygen saturation with respect to a baseline, heart rate, respiratory rate, and airflow, amongst others.

Illustrative images of the wearable sensors are shown in Figures 1 and 2. A full system diagram is shown in Figure 3.

Figure 2: Volunteer sleeping while wearing the sensors

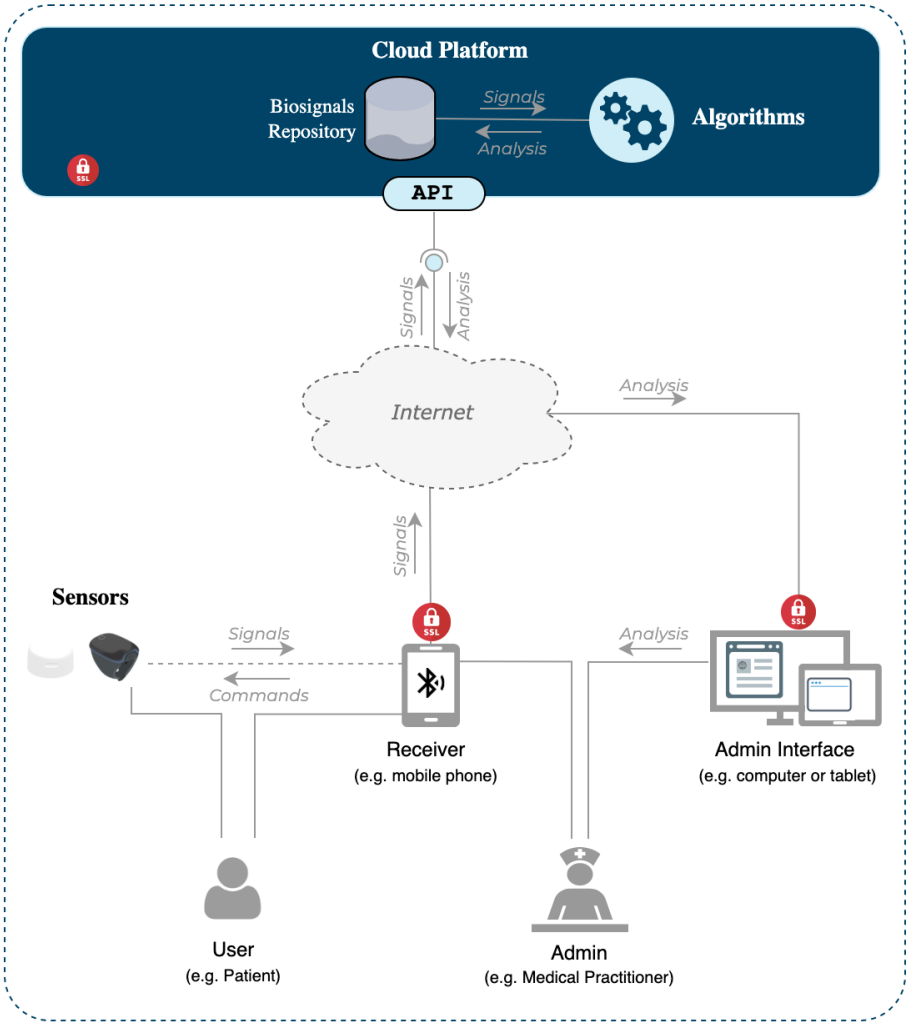


Figure 3: Full system diagram

4.3 Risks and Benefits

- Risks:
  - Sensors that attach to the body, even with medical grade adhesive (as is the case in AcuPebble systems), can cause a minor allergic reaction if the patient happens to be allergic to the components of the adhesive.
  - As with any medical device, the outputs of the system are not 100% accurate.
- Benefits:
  - The system (with the exception of the part that is only accessible to healthcare professionals) can be used by patients themselves unsupervised at home, without the need of prior training. The device can also save interpretation time leading to faster subsequent interventions.
  - As per the patient's feedback, the system is significantly more comfortable to wear and use than current home-diagnosis gold-standard methods.

4.4 Basic technical specifications of AcuPebble 100 (neck sensor)

Weight	7 grams
Dimensions	2.9cm (diameter), 1.4cm (height)
Transmission band	2.402 GHz to 2.480 GHz
Battery type	Non-removable Lithium Polymer
Cleaning method	Alcohol wipes
Charger type	Micro-USB
Means of attachment	AcuPebble single use medical adhesives only
Place of attachment	Front of the neck

4.5 Basic technical specifications of OxiPebble 100 (finger/forehead SpO2 sensing channel)

Weight	6 grams
Dimensions	17 x 24 x 13mm
Transmission band	2.402 GHz to 2.480 GHz
Battery type	Non-removable Lithium Polymer
Cleaning method	Alcohol wipes
Charger type	Micro-USB
Means of attachment	AcuPebble single use medical adhesives only
Place of attachment	Finger tip / Forehead
Default settings	Not applicable
Alarm	Not applicable
Wavelength / Max emission power	660nm/880nm, 9.8mW/6.5mW
Oxygen level range	70% to 100%
SpO2 accuracy	Within 3% ARMS
Rated system voltage	3.7VDC
RF technology	Bluetooth LE 1m
Antenna type	Chip, 1.0 dBi gain

5. System Requirements

5.1 System requirements for running the mobile application

The system can only be used with certain types of mobile devices. Performance and usability can both be affected if this is not the case. Check with your distributor whether the one you have would be suitable, or alternatively to get a suitable one for you.

A Wi-Fi or mobile network connection is required in order to set up the application and upload patient test results.

- Minimum:
  - Bluetooth 4.0 (Hardware BLE support)
  - Support for Android 6.0+ and iOS
  - 1 GB storage
  - Wi-fi
- Recommended:
  - Bluetooth 4.2

5.2 System requirements for charging the sensors

A micro-USB charger which is able to provide more than 80mA of current must be used. Otherwise the safety and performance of the system is not guaranteed.

5.3 System requirements for accessing the web application

A computer with a compatible web browser installed and an internet connection is required in order to access the web application interface. Acurable Ltd does not guarantee the compatibility of the web application with browsers and versions not specifically listed as compatible. If you want to use a different browser or version, please first contact your distributor to verify its compatibility.

- List of compatible web browsers:
  - Recommended: Chrome 63+, Firefox 67+, Safari 11.1+, Edge 69+
  - Minimum requirement: ES6 compatible browsers

5.4 System requirements for interfaces and communication protocols

Please follow the instructions below to maintain the device protected against cybersecurity threats.

5.4.1 How to inform about cybersecurity incidents

- The system's web application and mobile application have specific screens and messages to notify the user of possible issues, with instructions about how to proceed in each case and how to contact technical support when needed.
- If Acurable identifies a cybersecurity incident, the user will be informed via email of the issue and instructed on what to do by Acurable or your distributor.
- If you have experienced a cybersecurity incident (eg: user account compromised), please inform Acurable by contacting your distributor or by sending an email to support@acurable.com.

5.4.2 How to maintain the device cybersecurity

SYSTEM COMPONENT	INTERFACES/PROTOCOLS AVAILABLE	INSTRUCTIONS
Web application	· Web interface accessible via compatible web browser. · Secure communication with web browser via HTTPS protocol. · Secure user authentication via username, strong password and ReCaptcha.	· Use a compatible web browser (list available in this User Manual) and keep it up to date. · Keep the user authentication details secure and enable two-factor authentication.
Mobile application	· iOS/Android application installed on compatible mobile device. · Secure communication with AcuPebble cloud platform via HTTPS protocol. · Secure user authentication via username and strong password. · Secure communication with neck and finger sensors via encrypted Bluetooth protocol (BLE).	· Enable mobile application permission for internet access (WiFi or SIM) and Bluetooth access (BLE). · Keep the AcuPebble mobile application up to date. The mobile application will instruct the user when an update is required.
Wearable sensors	· Small wearable sensor to be attached to the front of the neck. · Small wearable sensor to be attached to the finger/forehead. · Secure communication with mobile application via encrypted Bluetooth (BLE). · Micro-USB port enabled only for charging and disabled for data transfer.	· Keep the neck/finger/forehead sensor firmware up to date. Security updates, or any other updates, are performed wirelessly (OTA). The mobile application will notify the user when an update is required.

6. How to use AcuPebble Ox200 step by step

The system works together with a mobile application. It is worth noting that most of the instructions contained in this manual do not need to be read if the instructions in the mobile application are followed. More specifically, sections 6.3, 6.4 and 6.5 are covered in the app.

In addition, this symbol has been added to all those sections that are also self-contained in the mobile application.

6.1 When receiving your AcuPebble Ox200

When unpacking, check to make sure that all items are in good condition, and that all third party ordered accessories correspond to the delivery note.

6.2 Setting up AcuPebble Ox200 for the first time

The sensors operate in combination with a mobile application. The mobile application should be installed in a mobile receiver, for example a mobile phone or tablet, compatible with the minimum requirements specified in this document.

- If you want to use the patient mobile phone or tablet to conduct the sleep study, make sure it is compatible with the minimum requirements.
- If you want to provide a mobile receiver to the patient to conduct the sleep study:
  - Acurable can procure a phone or equivalent receiver device and set up the system for you.
  - You can send us your mobile receiver(s) and we will set it up for you.
  - Alternatively, if you prefer to do it yourself, please follow the instructions below carefully.

6.2.1 Set up the mobile application

- Switch on the mobile receiver device (eg: mobile phone or tablet).
- Connect the mobile device to a wi-fi or mobile network to access the Internet.
- Open Google Play (for Android devices) or the App Store (for iOS devices) and search for “AcuPebble (OSA)”. Alternatively you can open the mobile device web browser and enter the following URL in the navigation bar, then press “Enter”: https://acurable.com/products/sleep-apnoea/download
- Press the “Download” button and download the app to the mobile device.

- After installing the application, a new icon with the text "AcuPebble (OSA)" will appear on your mobile device main menu. Press it to open the application.
- The mobile device and application are now ready to conduct sleep studies. The app will not allow the user to proceed unless the sensor is considered to be ready to complete a full night test, and it will guide the user on actions to be taken if this is not the case.

6.3 Using the mobile application

There are 3 steps required to complete a sleep study with AcuPebble Ox200:

- Create a sleep study
- Conduct a sleep study
- Upload a sleep study

In the following subsections we detail each step.

6.3.1 Create a sleep study

Healthcare professionals can create a new sleep study using the mobile or web applications.

- The steps to create a sleep study using the web application are detailed in Appendix D.
- The steps to create a sleep study using the mobile application are detailed in Appendix E.

6.3.2 Conduct a sleep study

Patients can conduct a sleep study using their own mobile phone/tablet, or using a mobile receiver already setup.

- If the sleep study is conducted using the patient's own mobile phone or tablet, the patient needs to activate the sleep study using a code before being able to conduct it. The steps to activate the sleep study using the patient's mobile phone are detailed in Appendix F.
- If the sleep study is conducted using a mobile phone or tablet already setup, the patient can undertake the sleep study directly.

The steps to conduct a sleep study are detailed in Appendix G.

6.3.3 Upload a sleep study

After conducting the sleep study, the data recorded needs to be uploaded for analysis.

- If the sleep study is conducted using the patient's own mobile phone or tablet, or a mobile device with an internet connection, the patient will upload the data.
- Otherwise, the healthcare professionals will upload the data after the patient returns the system.

The steps for both the healthcare professional and patient to upload a sleep study using the mobile application are detailed in Appendix H.

6.3.4 Terminating the operation

The operation of the system can be terminated by fully closing out the app in the mobile receiver (phone or tablet). The specifics on how to do this will depend on the exact model of your phone/tablet. If you need any assistance on this please contact either your terminal manufacturer or Acurable.

6.4 How to use the AcuPebble neck sensor

6.4.1 How to put on the neck sensor

The AcuPebble neck sensor is attached to the body with a medical grade adhesive. Every adhesive is single use. Once the adhesive is detached, it CANNOT be used again. Hence, if by mistake the sensor is attached in the wrong location, and needs to be repositioned, the adhesive MUST be replaced, regardless of the time it was in the wrong position. Also, if the adhesive is mistakenly touched in the middle while peeling or positioning the sensor, it must be replaced.

Prior to attaching the AcuPebble neck sensor, the location where it is going to be placed must be cleaned and dried. This can be done with either water and soap, or, if in clinical settings, with typically used alcohol wipes.

DO NOT use wipes with chlorhexidine to wipe the neck, since this affects the performance of the adhesive and the sensor will fall off.

This is especially important if the patient has used any kind of cream or makeup in that location. The skin must be totally free of those. Also, if the sensor is intended to be attached on a hairy surface, this must be shaved.

For use on intact skin only.

The AcuPebble sensor enclosure together with the adhesive is a floating applied part (i.e. a part that in normal use necessarily comes into physical contact with the user).

The sensor can be attached by peeling off the adhesive, holding it from the sides and fixing it to the desired location, applying a slight pressure for a couple of seconds.

In the mobile app, the instructions to put on the sensor are provided in the form of an animated video. Appendix A details each one of the instructions provided to the user.

6.4.2 How to change the adhesive

In the mobile app, the instructions to replace the adhesive will be provided in the form of an animated video. Appendix C details each one of the instructions provided to the user.

6.4.3 Sensor location

The AcuPebble neck sensor should be placed on the neck above the suprasternal notch (2 or 3 cm, where the trachea can be felt around that area above the notch). If this location is not possible, the closest to it, whilst as far as possible from arteries.

In the mobile app, the instructions detailing the location to put on the sensors will be provided in the form of an animated video. We detail in Appendix A each one of the instructions provided to the user.

When removing the adhesive from the neck a slight redness might appear in the location it was placed (similar to the redness that would appear in that user when taking off many other medical plasters from other parts of the body). Unless the patient has got an unknown allergy to acrylate this effect should not cause discomfort and should be temporary.

6.5 How to use the OxiPebble sensor (PPG/SpO2 sensing channel)

6.5.1 How to put on the sensor

The OxiPebble sensor is attached to the body with a medical grade adhesive. Every adhesive is single use. Once the adhesive is detached, it CANNOT be used again. Hence, if by mistake the sensor is attached in the wrong location, and needs to be repositioned, the adhesive MUST be replaced, regardless of the time it was in the wrong position. Also, if the adhesive is mistakenly touched in the middle while peeling or positioning the sensor, it must be replaced.

Prior to attaching the OxiPebble sensor, the location where it is going to be placed must be cleaned and dried. This can be done with either water and soap, or, if in clinical settings, with typically used alcohol wipes.

DO NOT use wipes with chlorhexidine to wipe the skin, since this affects the performance of the adhesive and the sensor will fall off.

This is especially important if the patient has used any kind of cream or makeup in that location. The skin must be totally free of those.

For use on intact skin only.

The OxiPebble sensor enclosure together with the adhesive is a floating applied part (i.e. a part that in normal use necessarily comes into physical contact with the user).

The sensor can be attached by peeling off the adhesive and attaching the adhesive part to the tip of the index finger (palms up when attaching) or the forehead.

In the mobile app, the instructions to put on the sensor are provided in the form of an animated video. Appendix B details each one of the instructions provided to the user.

6.5.2 How to change the adhesive

In the mobile app, the instructions to replace the adhesive will be provided in the form of an animated video. Appendix C details each one of the instructions provided to the user.

6.5.3 Sensor location

The OxiPebble sensor should be placed on the tip of the index finger or on the forehead.

In the mobile app, the instructions detailing the location to put on the sensor will be provided in the form of an animated video. We detail in Appendix B each one of the instructions provided to the user.

When removing the adhesive from the finger/forehead a slight redness might appear in the location it was placed (similar to the redness that would appear in that user when taking off many other medical plasters from other parts of the body). Unless the patient has got an unknown allergy to acrylate this effect should not cause discomfort and should be temporary.

6.6 Accessing diagnostic data

The diagnostic data can be accessed via a secure web application. The steps to access diagnostic data are detailed in Appendix I.

Depending on the service plan the user has contracted with Acurable, the user may be able to access different levels of information.

6.6.1 Historic information

In the web app, there is also the option of accessing a historic list of patients tested, so that the information about a specific patient can be clicked on directly without having to manually enter the identifier number (Note that this list is still identifier based, since no personal information is recorded by the system).

7. Charging the Batteries

The batteries in the sensors are expected to last over 12 hours when used for sensing after having been fully charged. We advise that you charge the batteries for at least an hour before carrying out an overnight test. The batteries can be charged by connecting a micro-USB charger to the micro-USB connector (DC port. See Figure 4 below). If you do not own a suitable charger, you can ask your distributor to get one for you. Note that the DC port is solely intended for connection to the micro-USB charger.

Whilst the batteries are being charged, and until they are fully charged, a shining orange light will be seen through the enclosure. You might need to surround the enclosure with your hand to see it properly under very bright room lighting conditions. The app will guide you through this. Once the batteries are fully charged the light will turn green.

The app will also warn you if either battery is not sufficiently charged to carry out an overnight test.

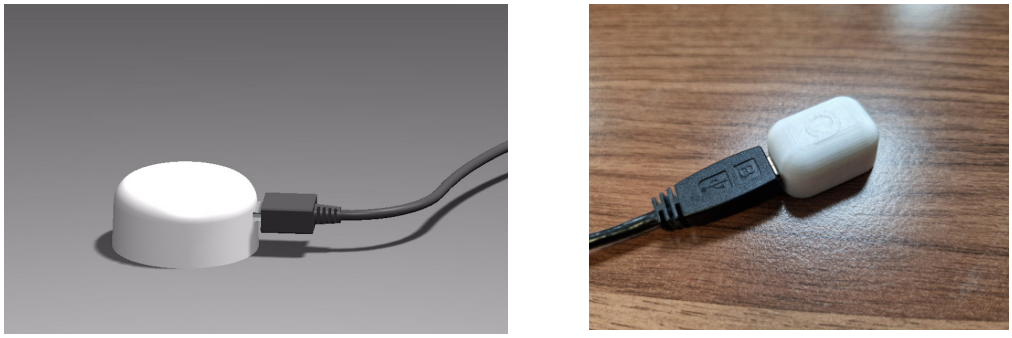


Figure 4 : Sensors connected to micro-USB charger

7.1 Battery levels

The sensors use a Lithium-Polymer battery. The use-life of the device is going to depend on how often the device is charged, since the battery is able to provide enough capacity for it to operate for up to 500 recharging cycles. Hence, assuming daily use, the device is expected to function for over a year; less frequent use may result in longer operation. However, the device should not be left unused for long periods of time. Following the recommendations of the battery manufacturers if the device is stored for extended periods, this should be fully charged, fully discharged and fully charged again, at least once every 90 days.

The system will warn about power limitations prior to starting any test. Please do charge the batteries if this warning appears.

If after charging the device, this warning persists immediately after disconnecting it from the charger, please contact Acurable Ltd to arrange for a replacement, since that might mean that the device has reached the end of its life.

7.2 Expected life (Expected failure time)

Once the battery reaches capacity/voltage levels that would not allow a test to be completed, this would be detected by the mobile app, in the same way the app detects when the battery is not charged to a level that would allow the device to operate continuously for a full test duration. Should the patient have the device when this happens, the only effect this will have is that a new sensor will need to be provided for the app to allow the test to take place.

8. Software Updates 

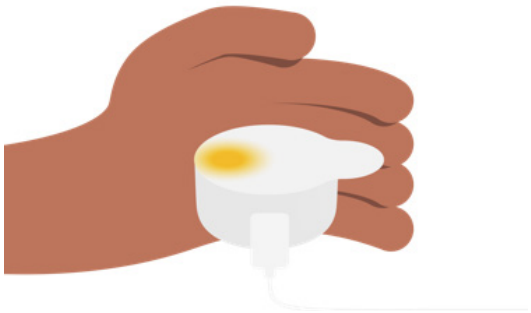
Whenever there is a mandatory software update available for the system, an alert will appear when accessing the “doctor/authorised person” mode of the app. The update must be completed before the user can continue with the application.

9. Security

To ensure data is kept secure, all healthcare professionals accessing the system through either the web or mobile applications must have a registered user account, which is accessed using a unique email address and secure password. In addition, users are encouraged as best practice to enable two-factor authentication to further protect the security of their accounts.

10. Troubleshooting

PROBLEM	POSSIBLE REASON	WHAT TO DO
I cannot login to the mobile application.	Either: · the internet connection is not working, or · your login/password are not valid	· Go to the phone/tablet settings and make sure the phone/tablet is connected to the internet via Wi-Fi and that the Wi-Fi signal strength is good. Otherwise try moving closer to the Wi-Fi router. · Then make sure your login details are correct. If you don't have login details, contact your organisation so they can create them for you. If you have login details but have forgotten them, use the reset option in the application to create a new password.
The wireless communication seems to be failing and I cannot connect the mobile application to the sensors.	Either: · the sensor is too far away · there are other electronic devices close to the sensor · the sensor is not charged, or · the mobile phone/ tablet you are using has Bluetooth disabled, or · the mobile application does not have permission to use Bluetooth	· Move the sensor next to the mobile phone/ tablet, and move any other electronic devices more than 30cm away from the sensor and mobile phone/tablet. · Charge the sensor by connecting it to a power supply, then verify your phone/tablet settings to make sure Bluetooth is enabled. · Finally, access the AcuPebble mobile app settings and make sure all the permissions are enabled. For Android devices, Bluetooth cannot work unless location permission is granted.

PROBLEM	POSSIBLE REASON	WHAT TO DO
I charged the sensor but the mobile app still says it is not charged.	Either: · you did not charge the sensor enough, or · the charger you used was not compatible so the sensor did not charge	· Charge the sensor again. Make sure the charging light is on and that the charger is connected on the other side to a suitable power source that would be able to provide 80mA current (for example, if the charger is connected on the other side to certain USB splitters with other devices the current might be limited). If the problem persists, change the charger, in case this is unnoticeably broken.
The sensor light does not come on when charging.	Either: · the charger is not properly plugged into the sensor, or · the light is on, but you cannot see it due to high ambient luminosity	· Make sure the charger is properly attached to the sensor and the electricity socket. · You may need to shield the sensor with your hand to see if the light is on: 
The sleep study does not upload.	Either: · the internet connection is not working, or · it is too slow to complete the upload	· Go to the phone/tablet settings and make sure the phone/tablet is connected to the internet via Wi-Fi and that the Wi-Fi signal strength is good. Otherwise try moving closer to the Wi-Fi router. · If the upload starts successfully but never finishes, try using a different Wi-Fi network or wait a few minutes and try again.

If the problem persists or you experience an issue not described above, please contact your distributor for further assistance.

11. Cleaning and Maintenance

11.1 Cleaning and disinfection

Regardless of whether a sleep apnea patient is known to have an infectious disease or not, since the sensors are reusable, for hygiene reasons, they should be cleaned in-between uses by different users. In order to do this, wipe the enclosure of the sensors with an alcohol wipe (70% isopropyl alcohol).

When the adhesives are on, both sensors are at least IP22 in terms of water ingress. This means that they are protected against insertion of fingers and will not be damaged or become unsafe during a specified test in which it is exposed to vertically or nearly vertically dripping water.

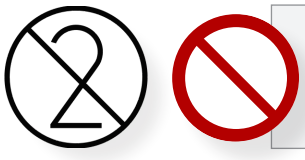
After cleaning, the devices must be visually examined in a well-lit area. If the devices appear visibly soiled, then further cleaning is required and the process should be repeated. If after several attempts the devices cannot be satisfactorily cleaned, or any signs of damage to the enclosure are noted, the devices must be taken out of use and disposed of safely, as described in section 16.

If the adhesive is not on, make sure not to get any liquid into the hole at the bottom of the AcuPebble neck sensor enclosure. If by mistake liquid gets into that hole, do not use the system. Contact your distributor, or Acurable directly.

With the adhesive off, the sensors comply with IP protection class “20”. This means that the sensors are NOT waterproof. Also protect them from dust and dirt.

Do not submerge any sensor in water or any other liquid.

Do not clean any sensor with acetone or other volatile solutions.



DO NOT reuse the adhesive.

11.2 Use and maintenance of sensor batteries

The sensors operate with a rechargeable Lithium-Polymer battery. These batteries have been tested for safety by the battery manufacturers as per IEC 62133-2. The batteries offer a long lifetime (approximately 500 charges), are not susceptible to memory effects and are ecologically friendly. Every charging cycle is counted as a complete charge. It takes approximately 2.5 hours (150 minutes) to charge a full battery.

When the sensors are being charged an orange light will shine through the device enclosure. This light will turn green when the battery is fully charged and still connected to the charger. Note that it is not necessary to fully charge the batteries for the system to be ready for a night test. The mobile app will however only let the user continue with the tests once the batteries have reached enough level of charge.

Never dispose of the system in domestic waste. It is strictly forbidden to dispose of Lithium batteries in domestic waste. Please return it to your distributor or hand them in at your local waste disposal point.

11.3 Expected life of the device

If used and stored according to these instructions for use, the sensors can be re-used up to 500 times. Once the batteries reach capacity/voltage levels that would not allow a test to be completed, this would be detected by the mobile app, in the same way the app detects when the batteries are not charged to a level that would allow the device to operate continuously for a full test duration. Should this happen, the device must be replaced.

Before every use, the device must be visually examined in a well-lit area. If the enclosure appears corroded, cracked or otherwise damaged, the device must be taken out of use and disposed of safely, as described in section 16.

12. Storage and Transport

Always carry and store the device in a pouch, box or some other kind of alternative protective cover. The AcuPebble neck sensor should always be stored with an adhesive on.

Once opened, make sure to always store and transport the sensors with an adhesive on, and in a separate protective bag or container, to prevent, for example, a thin-pointed object from breaking the adhesive and penetrating the hole at the bottom of the enclosure. Additionally, wearable electronic sensors should be wrapped up in bubble envelopes.

The following environmental conditions must be respected during transport and storage:

- Temperature between -25°C and +70°C (-13°F and +158°F).
- Humidity between 20% and 75%.
- Atmospheric pressure between 70 kPa and 106 kPa.

Additional environmental conditions:

- If the device is going to be stored for more than 3 months but less than a year, the storage temperature should be between -5°C and 25°C (23°F and 77°F).
- If the device is going to be stored for less than three months the storage temperature should be between -10°C and 40°C (14°F and 104°F).
- During long periods of storage, the device should be fully charged, fully discharged and fully charged again at least once every 180 days.

For shipping, the device must be protected by placing it in its original packaging or, alternatively, by covering with protective wrapping. Once protected, the device should be placed inside a standard cardboard shipping box, with padding or equivalent to avoid sudden vibrations or movements. Additionally, if the shipment contains 3 or more sensors, the shipping box should comply with the labelling requirements for international transportation of new small size Lithium batteries contained in equipment, specifically:

- For all transport methods, the shipping box should have affixed the UN3481 handling mark.
- For air transport, the shipping box should also have affixed a transport document containing a General warning statement and an Air-waybill notice.
    - General warning statement: “The package contains Lithium cells or batteries; the package must be handled with care and a flammability hazard exists if the package is damaged; special procedures must be followed in the event the package is damaged, to include inspection and repacking if necessary; For emergency information, call (+1) 833 502 0261.”
    - Air-waybill notice: “Lithium batteries, in compliance with Section II of PI967”.

13. Warranty

Acurable will only guarantee the Safety, Operation and Reliability under the following conditions:

- The system is used according to the instructions.
- The system is stored in a suitable environment.
- The system is not physically modified.
- The system is not put to charge more than once a day.

The system is guaranteed for 12 months.

Details about warranties will be specified in your contract with the manufacturer (or authorised representative when relevant).

14. Travel or International Use

This medical device has been authorised for use in the US. Use outside the US might result in infringement of national laws and hence must be not authorized.

15. Accessories

AcuPebble Ox200 requires the following accessories to operate:

- A micro-USB charger providing over 80mA of current (alternatively the sensors can be charged with a micro-USB cable connected to a device with a suitable port).
- A mobile phone or tablet or computer (see section 5.1 for required specifications).

AcuPebble Ox200's distributors can procure any of these accessories for you, or alternatively you can purchase them separately yourself. However, note that:

Acurable Ltd. does not guarantee the Safety, Reliability and Operation of AcuPebble Ox200 if incorrect devices are used.

Unlike third party oximeters, OxiPebble PPG/SpO2 sensor will not provide an output independently of AcuPebble Ox200, and does not provide visible outputs in real time.

16. Disposal of Parts

Devices must be disposed of according to local regulations for environmental protection.
Since the devices do contain Lithium batteries, domestic disposal is not allowed.

Never dispose of the devices in domestic waste. It is strictly forbidden to dispose of Lithium batteries in domestic waste. Please return the devices to your distributor or hand them in at your local waste disposal point.

17. Information about Radio Equipment Electromagnetic Compatibility

17.1 Wireless transmission

Sensors in the system use nRF52832 transceivers for fast and reliable data transmission. This transceiver chip is non-adaptive and uses GFSK frequency modulation in the frequency range 2.402 GHz to 2.485GHz. This is an ISM band which is available globally and is intended to ensure communication compatibility everywhere in the world. The effective radiated power when in operation of this integrated circuit is less than 7dBm e.i.r.p., with a maximum transmission power of +4dBm. The maximum data rate is 26 kbps and the transmission of data is encrypted using the AES-CCM encryption scheme.

The device is classified as Group 1, Class B as per EU and British Standard BS EN 55011:2016 (CISPR 11:2015); this is equipment suitable for use in locations in residential environments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

Guidance and Manufacturer's declaration- electromagnetic emissions

Emissions test	Compliance	Electromagnetic environment- guidance
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment		
RF emissions, CISPR 11	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby equipment
RF emissions, CISPR 11. Electromagnetic radiation disturbance limits	Class B Complies	The equipment is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes

For any further technical information about this integrated circuit you can also contact the manufacturers (https://www.nordicsemi.com/).

17.2 Electromagnetic Compatibility (EMC)

This product emits radio frequency energy, but the radiated power is very low, and has been tested and found to be in compliance with CISPR-11.

Although not affecting safety, other portable and mobile RF communications may however affect the optimum performance of the device, resulting in inconclusive sleep apnea test results (and consequently the requirement of having to repeat the test). The reason for this is that the device may suffer from interference from other equipment, even if that equipment complies with CISPR-11 radio requirements. To minimize the probability of this, wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies, etc. should be kept at least a distance “d” away from the equipment. The distance d can be calculated from the Table below.

Recommended separation distances to portable and mobile communication equipment

Rated power of the transmitter (W)	Separation distance (d) according to the transmission frequency (m)		
	150kHz to 80MHz d=1,2(P) 1/2	80 MHz to 800 MHz d=1,2(P) 1/2	800 MHz to 2.5 GHz d=2,3(P) 1/2
The equipment is intended to be operated in an electromagnetic environment, where radiated RF interference is controlled. The user can help in avoiding interferences by means of meeting minimum separation distances between portable and mobile RF communication equipment (transmitters) according to the maximum output power of the communication equipment			
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

17.3 FCC Compliance

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Acurable has not approved any changes or modifications to this device by the user. Any changes or modifications could void the user's authority to operate the equipment.

FCC ID (neck sensor): 2A258-AP100D05
FCC ID (finger/forehead sensor): 2A258-OP100P02

AcuPebble Ox200 is an electronic device. As for all electronic devices, its operation could be somewhat affected by interference from other electronic devices. Examples of typical devices which may cause interference include RFID tags, televisions, other cell phones, etc. In some cases, since electromagnetic signals are not visible, interference might be the result of non-obvious sources. In extreme cases, this interference might lead to data loss which could result in an invalid test. Should this be the case you can try to prevent this from happening again by:

- Placing all other electronic devices as far as possible from the sensor, as you can in the bedroom; or even better, outside the bedroom, if this is at all possible.
- Placing the mobile phone (or smart device where the app is running) as close as possible to where you are sleeping. The closer the mobile phone is to the sensor the stronger the signal it will get.

AcuPebble Ox200 has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

18. Information about Safety Testing

This device has been tested for safety and found to be compliant as per European/British Standards BS EN 60601-1:2006+A2:2021 and its associated relevant collaterals.

19. Adverse Events

No adverse events have been reported whilst using this product so far. However, it is important to note that this device should not be used by patients with a known allergy to medical adhesives, since the device is attached to the body with one, which cannot be replaced by any other form of attachment. Slight transitory redness typical of the one left when pulling an adhesive from the body (like other bandages) is not considered an adverse event.

20. Summary of Clinical Evaluation Results

A summary of clinical evaluation results can be found in the following peer reviewed open source publications:

- Nikesh Devani, Renard Xaviero Adhi Pramono, Syed Anas Imtiaz, Stuart Bowyer, Esther Rodriguez-Villegas, Swapna Mandal. (December 21st, 2021). Accuracy and usability of AcuPebble SA100 for automated diagnosis of obstructive sleep apnoea in the home environment setting: an evaluation study. Volume 11, Issue 12. doi: 10.1136/bmjopen-2020-046803

  Available at https://bmjopen.bmj.com/content/11/12/e046803

- Jesus Sanchez Gomez, Renard Xaviero Adhi Pramono, Syed Anas Imtiaz, Esther Rodriguez-Villegas, Agustin Valido Morales (January 19th, 2024). Validation of a Wearable Medical Device for Automatic Diagnosis of OSA against Standard PSG. Volume 13, Issue 2. doi: 10.3390/jcm13020571

  Available at https://pubmed.ncbi.nlm.nih.gov/38276077/

The SpO2 of OxiPebble in AcuPebble Ox200 complies with the FDA guidance on Pulse Oximeters (Premarket Notification Submissions 510(k)s and ISO 80601-2-61).

The Arms of the OxiPebble SpO2 validated in the range of 70% to 100% was 1.86 and 2.25 when used on the forehead and on the finger respectively.
The validation study was performed in agreement with the ISO 14155 and ISO 80601-2-61 SpO2 accuracy testing, where OxiPebble was compared against hemoglobin saturation (SaO2) in the radial artery. Twelve subjects of varying skin colour encompassing all the skin tones in the Fitzpatrick scale (except for scale 2) completed the study with total data points in excess of 200.
On the subject whose skin tone was the lightest (Fitzpatrick scale 1 and Monk scale 1), the Arms for the SpO2 is 1.63 and 1.44 when used on the forehead and on the finger respectively.
On the subject whose skin tone was the darkest (Fitzpatrick scale 6 and Monk scale 10), the Arms for the SpO2 is 0.66 and 1.36 when used on the forehead and on the finger respectively.

The Pulse Rate of OxiPebble in AcuPebble Ox200 complies with the FDA guidance on Pulse Oximeters (Premarket Notification Submissions 510(k)s and ISO 80601-2-61). The respiratory rate output signal should be interpreted together with other channels.

Two validation studies were done to assess the accuracy of the pulse rate.
The first validation study performed in agreement with the ISO 14155 and ISO 80601-2-61 on twelve subjects with 3 lead Electrocardiogram Philips MP70 as the reference device. The Arms was found to be 1.23 bpm in the range of 55-115 bpm for both when worn on the forehead and on the finger.
The second validation study performed following the guideline in ISO 80601-2-61 and ANSI AAMI EC13:2002. Functional tester Contec SpO2 Simulator MS100 (Contec Medical System) and simulated signal were used to validate OxiPebble in the range of 30-210 bpm where the Arms was found to be 0.81 bpm.

Validation of the body position output of AcuPebble Ox200 was done in two separate experiments: under controlled condition and during natural sleep. The body position output of AcuPebble Ox200 are Supine, Prone, Left, Right, and Upright. The first study was carried out at Imperial College London (ICREC ref.: 18IC4358) under controlled conditions. The overall accuracy of the position classification is 93.93%. The second study was conducted using data during natural sleep conditions from subjects that had been referred for diagnosis of obstructive sleep apnoea (OSA) to Virgen Macarena Hospital, Seville, Spain (Trial registration number: NCT04028011). The overall accuracy of the position classification is 79.00%. The same study evaluated the accuracy of the PSG system used conventionally in the hospital to diagnose patients (Philips Sleepware G3) in the same dataset. The Philips Sleepware G3 had an accuracy of 74.46%. In detecting supine versus non-supine position, the accuracy of AcuPebble was 83.59%, higher than the accuracy of the Philips Sleepware G3 (77.02%).

Validation of the respiratory rate output of AcuPebble Ox200 was done in three studies for the range of 4-30 breaths per minute (bpm). The first study was carried out at Imperial College London (ICREC ref.: 18IC4358) on 15 volunteers against a multi-parameter end-tidal CO2 capnography system with both no artefacts and artefacts condition. The overall RMSD of the respiratory rate output for this first evaluation is 2.78 bpm. The second study was carried out validating the respiratory rate output during natural sleep on 150 subjects referred for OSA diagnosis to Royal Free Hospital, London, UK (Trial registration number: NCT03544086). The overall RMSD for this second study is 2.46 bpm. The third evaluation was done on 21 patients being monitored for Chronic Obstructive Pulmonary Diseases (COPD) exacerbation in Royal Free Hospital, London, UK (Trial registration number: NCT04495062). The RMSD for this study is 2.55 bpm.

Validation of the respiratory effort of AcuPebble Ox200 was done on data collected from 150 subjects referred for OSA diagnosis to Royal Free Hospital, London, UK (Trial registration number: NCT03544086). The average agreement from two clinicians in manually identifying obstructive and central apnoeas is 96.8%. The accuracy to identify breathing segments with effort vs no effort was evaluated both using the channels of AcuPebble and separately using the RIP bands from the Embletta MPR Sleep System (reference cardio-respiratory polygraphy system used in the study) instead. This was 75.9% when the Embletta channels were used vs 96.3% when AcuPebble channels were used.

21. Contact

For questions, problems, feedback, or should you need any help with the system, contact us! We will be happy to hear from you.

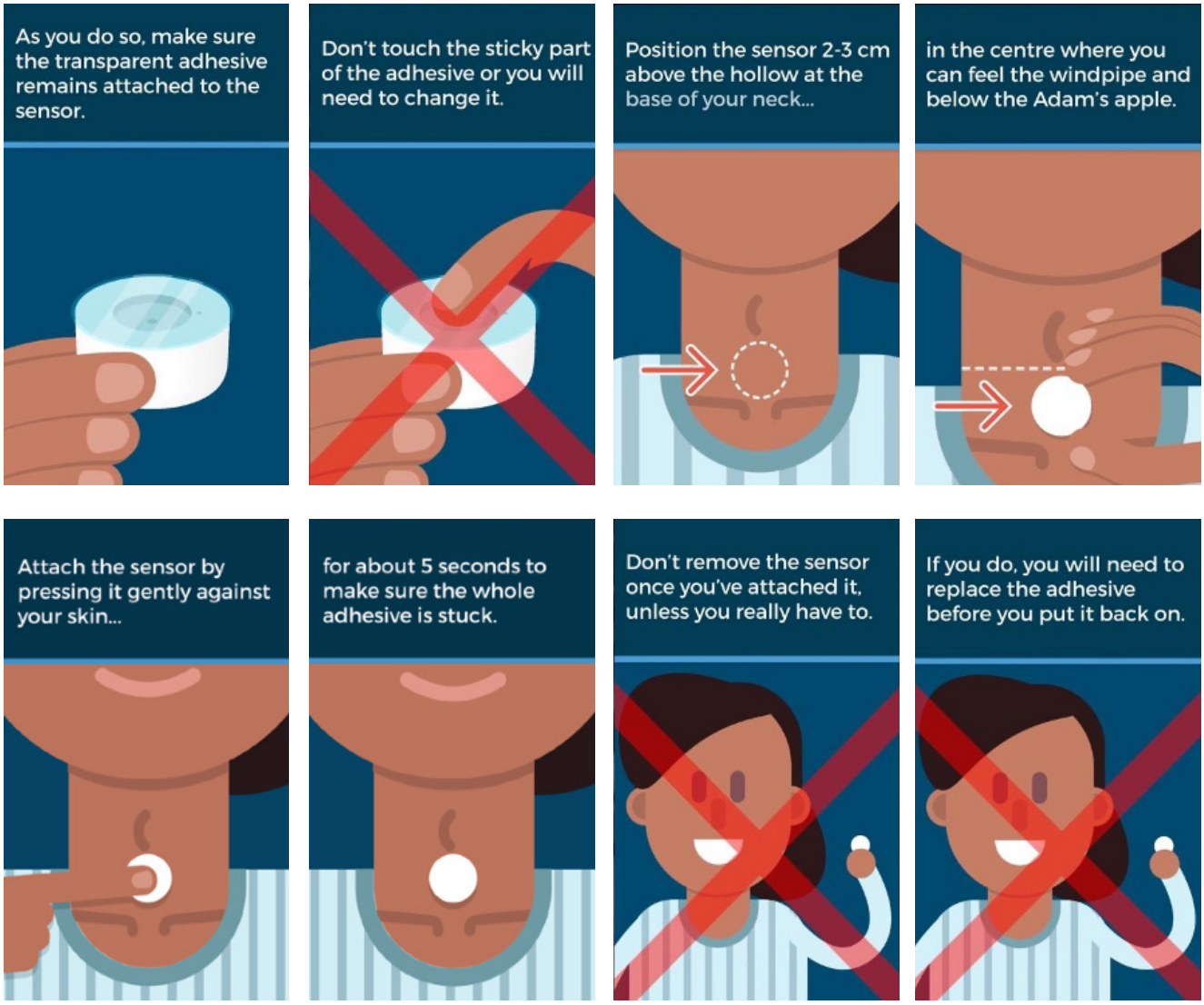
Our telephone-hotline offers help at:
Mon-Fri 09:00-18:00 +1 833 502 0261

Send us a message by email at any time:
support@acurable.com

Or send us a letter at:
Acurable, 2 Leman Street, London E1W 9US, United Kingdom

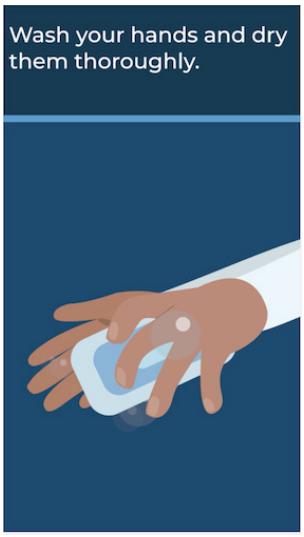
Appendix A: How to put on the AcuPebble neck sensor

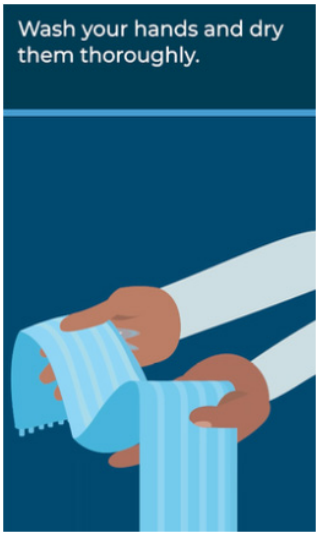
Instructions on how to put on the AcuPebble neck sensor are given in videos in the mobile app, as shown:

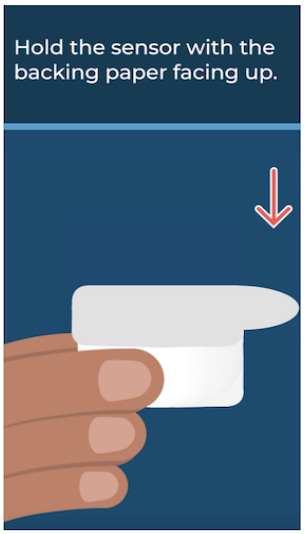


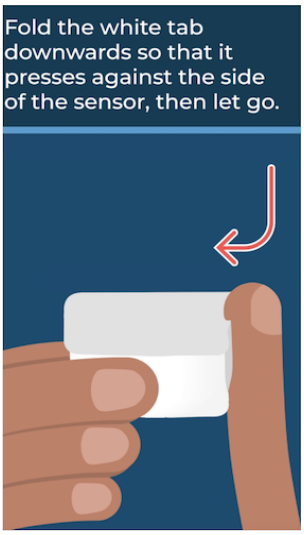
Appendix B: How to put on the OxiPebble sensor

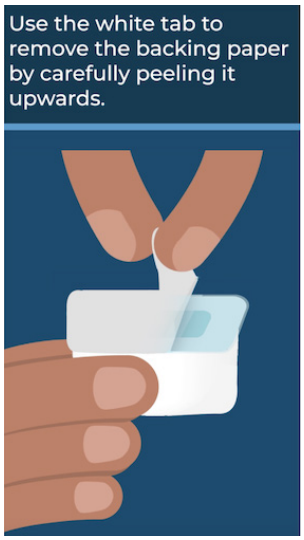
Instructions on how to put on the OxiPebble finger sensor are given in a video in the mobile app, as shown:

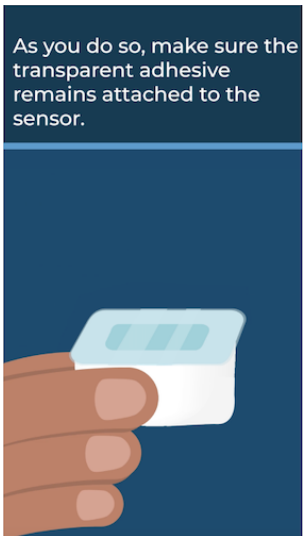


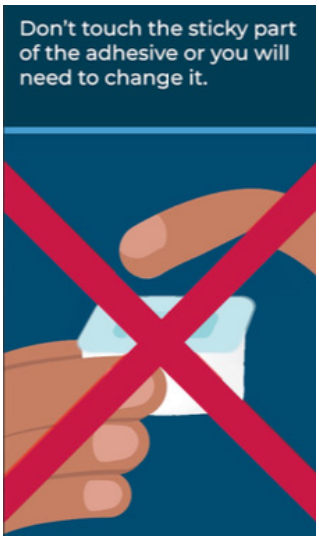


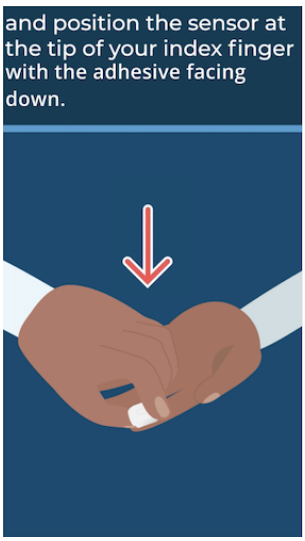


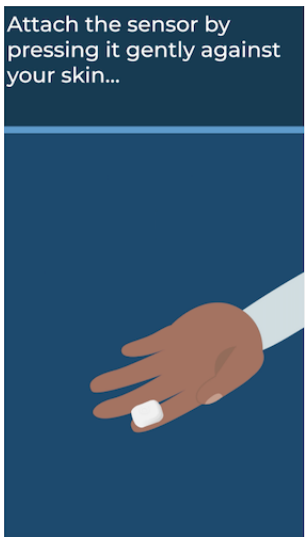


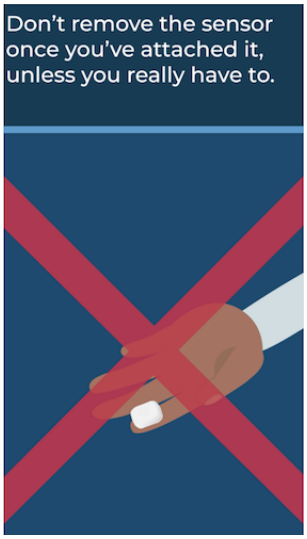






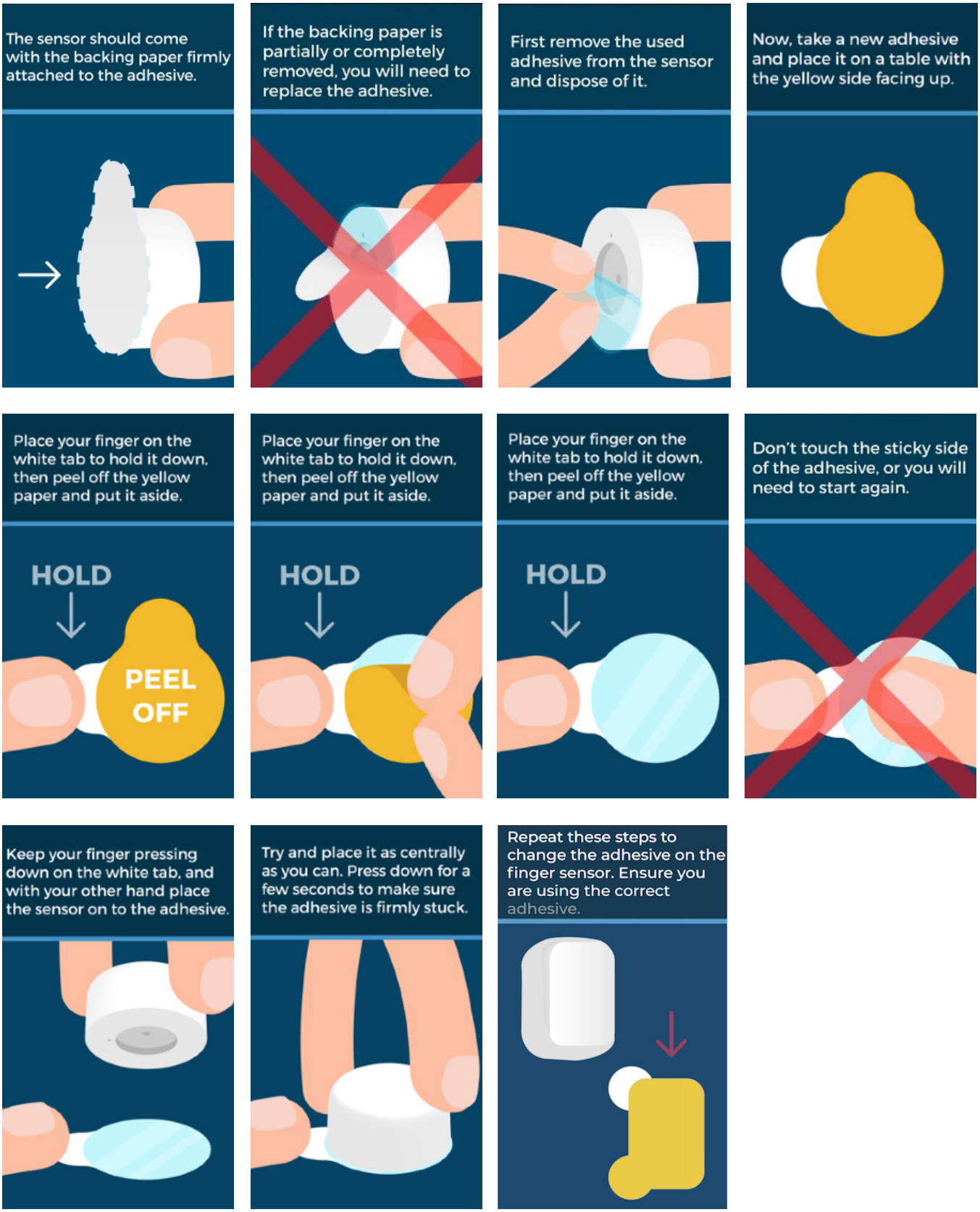






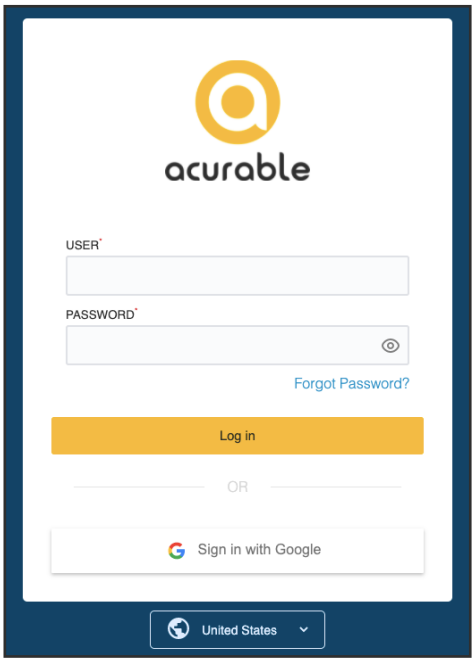
Appendix C: How to replace the adhesives

The steps for replacing the adhesives on both sensors are the same. These steps are explained in a video in the mobile app, as shown in the screens below.



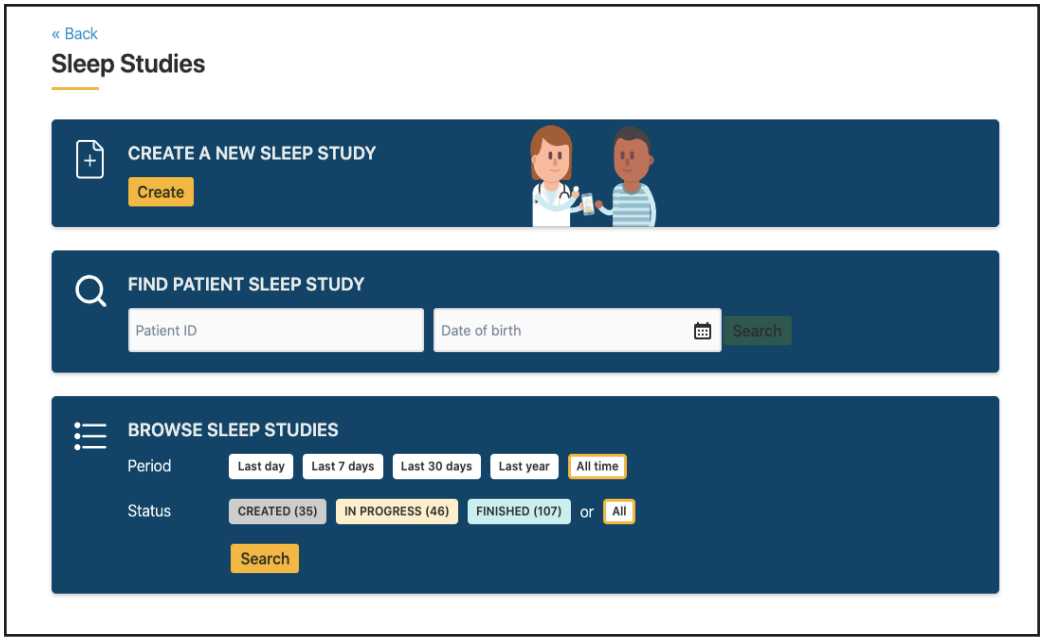
Appendix D: Create a sleep study using the web application

1. Go to the web app at https://cloud.acurable.com.



2. Enter your login details and press "Log in". If you've forgotten your password, you can reset it.

3. Select "Studies" in the main menu, then click on "Create".



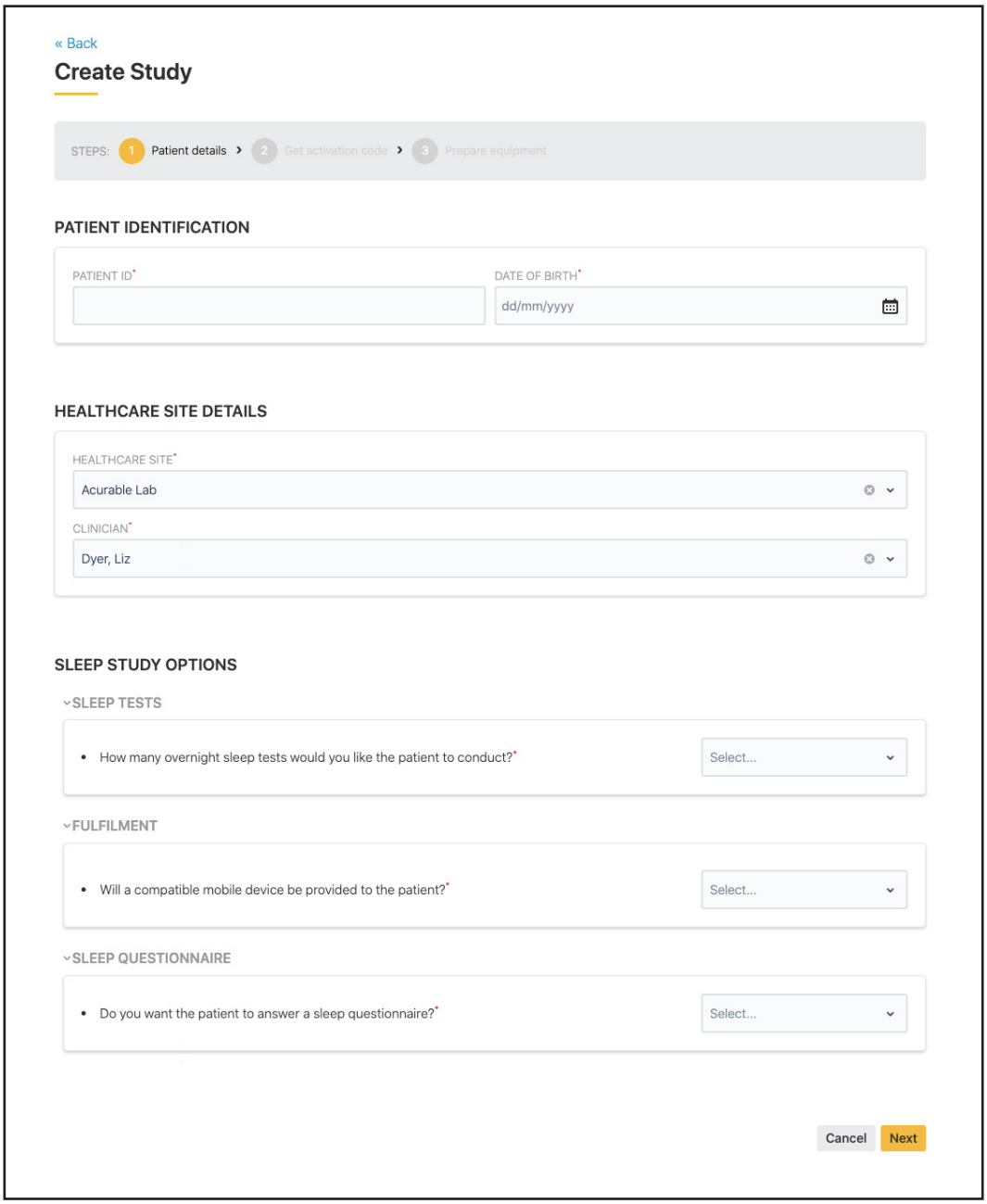
4. Complete the form with the following information:

   a. Patient identification: enter the patient ID and date of birth.

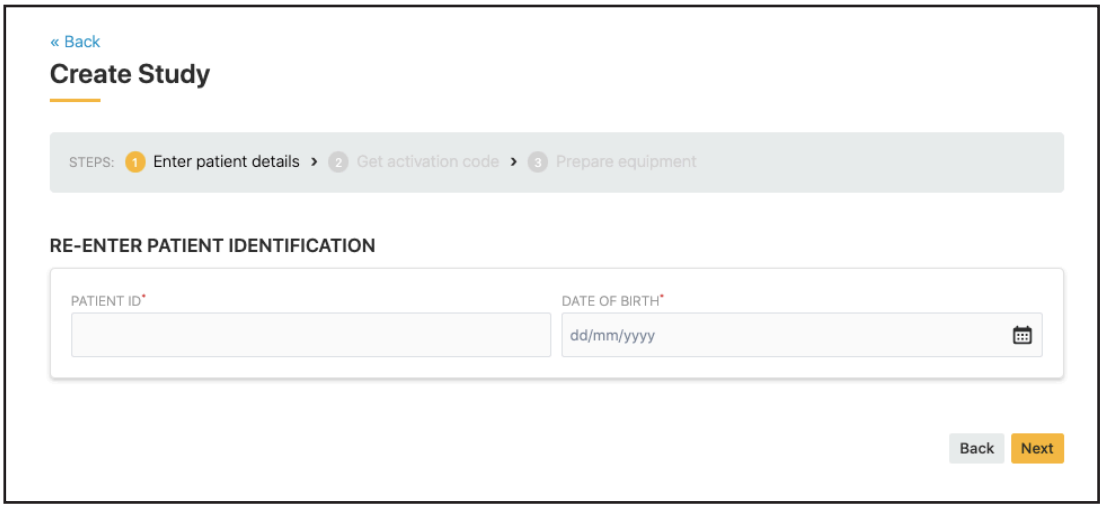
   b. Patient profile: answer the questions to provide more detail about the patient.

   c. Healthcare site details: select the healthcare site and requesting clinician for the study.

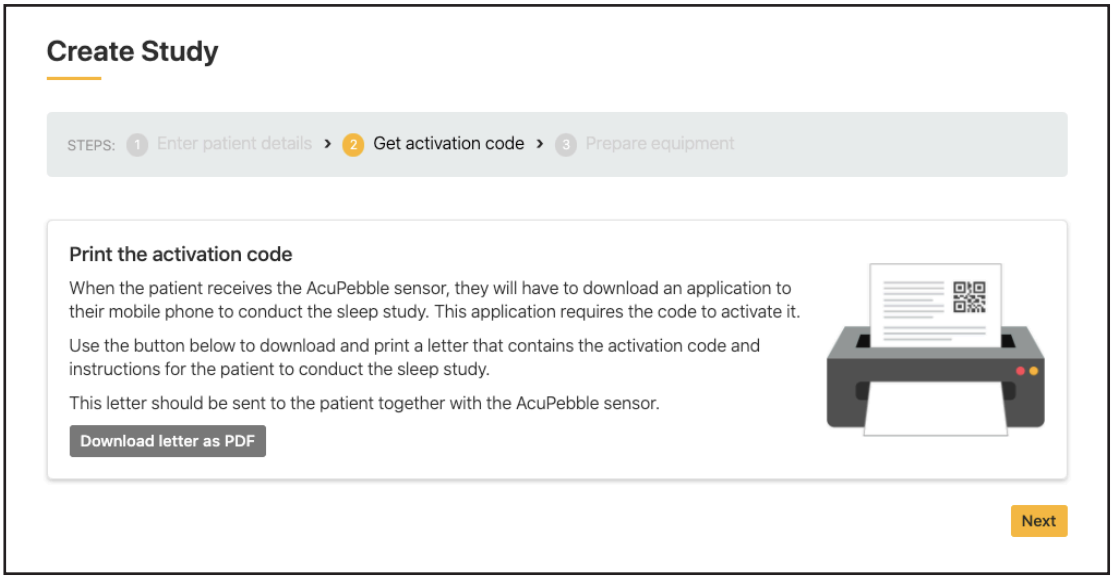
   d. Sleep study options: confirm if a mobile device will be provided to the patient, whether they need to complete a sleep questionnaire and how many sleep tests you would like the patient to conduct.



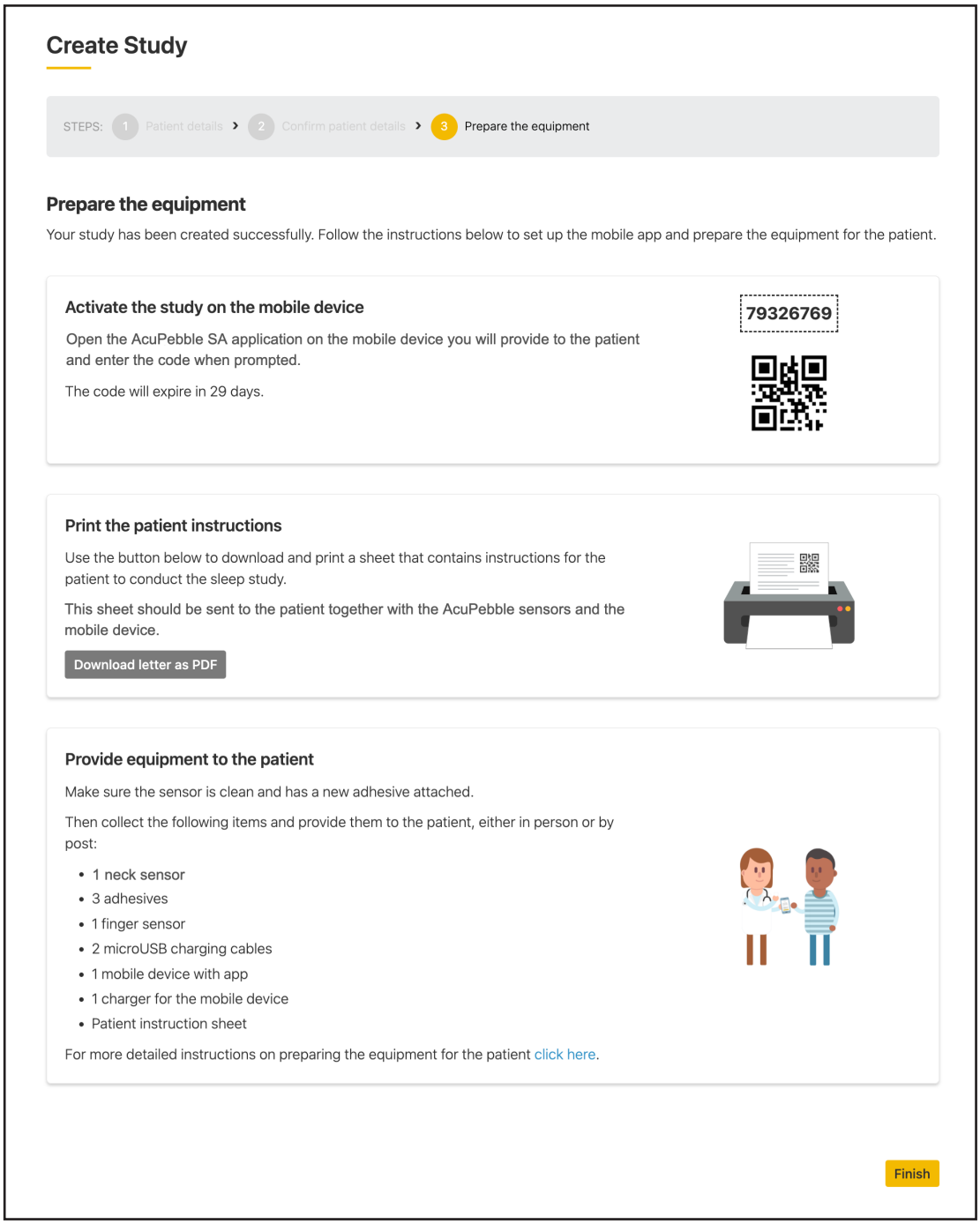
5. Re-enter the patient ID and date of birth, to confirm they are correct.



6. If the patient will be using their own phone to conduct the study: Print the activation code with instructions to send to the patient with the sensor.



7. If the patient will be using a hospital phone to conduct the study: An activation code will be displayed on screen in the web app. You will need to enter this in the mobile app on the hospital phone before giving it to the patient (see Appendix F).



8. Follow the instructions provided to prepare the equipment to be supplied to the patient. You will need to:

    a. Charge the sensors/accessories.

    b. Check the adhesive, and replace if necessary.

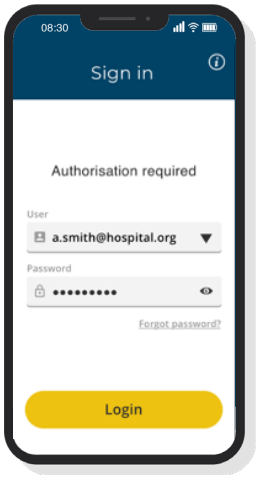
    c. Clean the sensors.

    d. Prepare all the equipment for posting or handing to the patient.

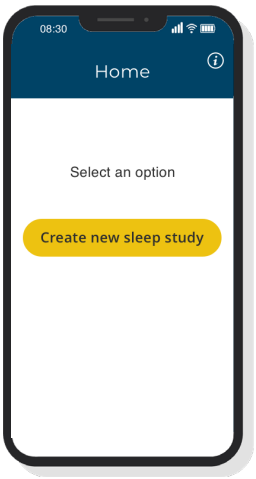
Appendix E: Create a study

Patients can conduct a sleep study using their own mobile device (patient mode), or using a mobile device provided by the healthcare professional already setup (hospital mode).

For studies to be conducted in hospital mode, you can use the mobile app to create a new study or load a study directly (previously created on the web app) on the device that the patient will use (see Appendix E).

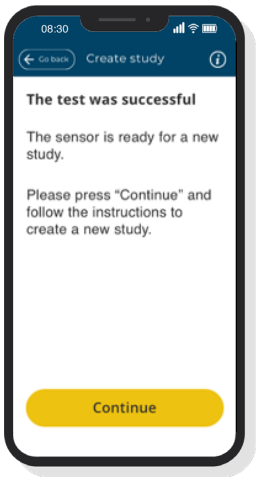


Enter your login details and press "Login". If you've forgotten your password, you can reset it. If you haven't received your login details, please contact your administrator or Acurable representative.

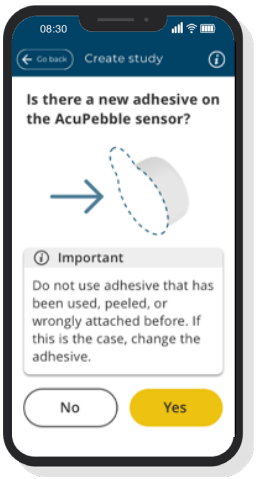


Select the option to create a new sleep study.

Press "Start", and the app will check the battery levels of the sensor and mobile phone and connectivity between the devices. If any action is required, the next screen will explain what you need to do.

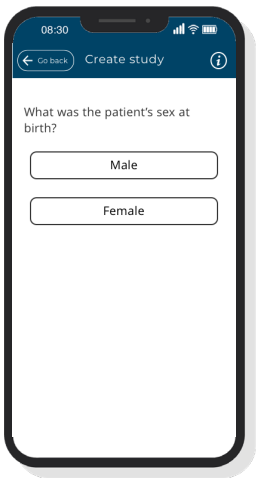


When the test is complete, press "Continue" to carry on.

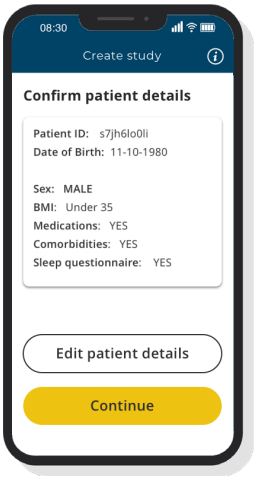


Check that the sensor has a new, unpeeled adhesive. If it does, press "Yes". If it doesn't, press "No" and the app will provide video instructions explaining how to replace the adhesive.

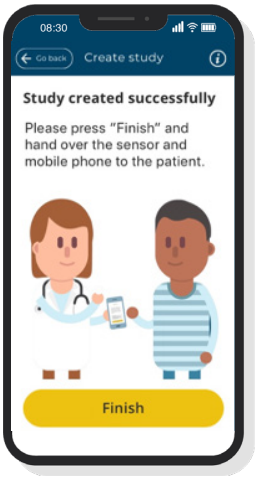
Step 1 - Enter the patient ID and date of birth, and press "Submit".
On the following screen, you will need to re-enter these details.



Step 2 - Answer the questions in the app to complete the patient profile for the study. This includes the number of tests you would like the patient to conduct.



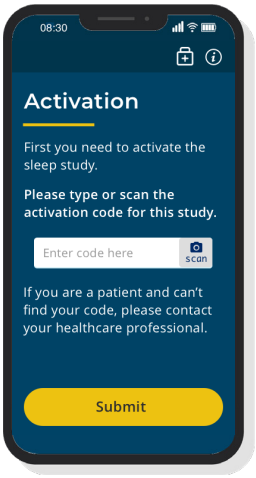
Review the information and check that all the details are correct. You can go back and edit them if you need to.



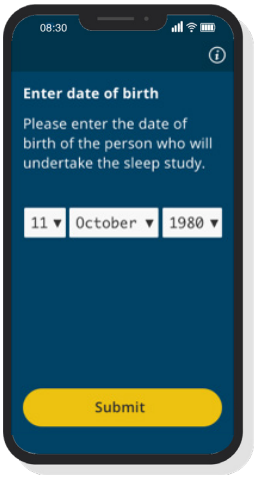
The study has now been created, and the sensor and mobile phone can be provided to the patient to conduct the study (Appendix G).

Appendix F: Activate a sleep study

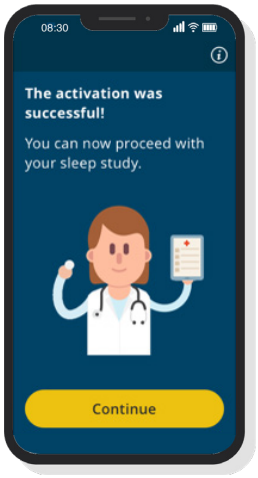
If the study is to be conducted in patient mode, the patient will first need to install the AcuPebble app on their own mobile device from the App Store or Google Play (see section 6.2.1). When they open the app, they will be asked to activate their sleep study, using the code that was generated by the web app (Appendix D) and supplied to them with the sensor. Healthcare professionals who created a study in the web app can also enter the code here to activate the study before supplying the phone to a patient in hospital mode.



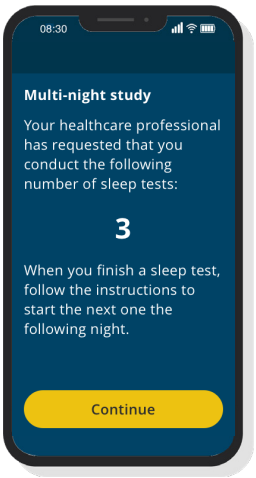
When the patient has installed the mobile app on their own phone, they will need to type or scan the activation code supplied with the sensor in order to start the study, then press "Submit".



Patients should now enter the date of birth of the person undertaking the study, and press "Submit". If the activation is being completed by a healthcare professional, the patient will enter their date of birth later.



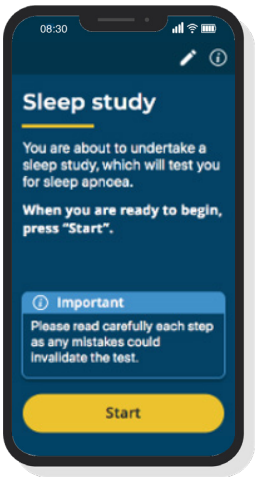
The mobile app will check the code and the date of birth entered, and if they match a new study in the system, the patient can press "Continue" to begin the sleep study. If there is a problem, they will be advised on how to get help.



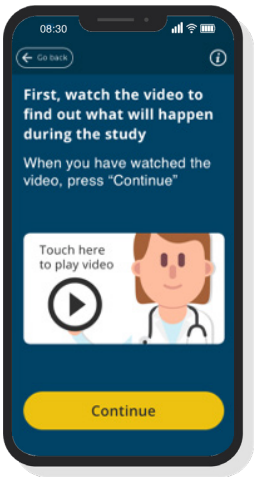
If the healthcare professional has requested that the patient completes more than one sleep test: the mobile app will advise the patient before they begin how many tests they need to do.

Appendix G: Conduct a sleep study

In both patient and hospital mode, once a sleep study has been created (Appendix E) or activated (Appendix F), the patient should follow the instructions in the mobile app to conduct the study.

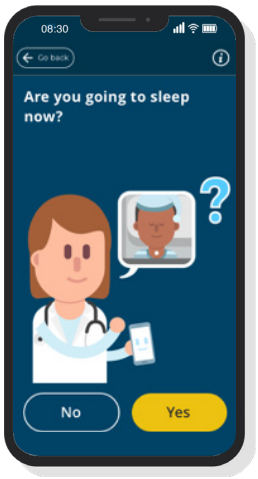


When they are ready, the patient should press "Start". The app will then check the battery charge levels of the AcuPebble sensors and mobile phone, and the connectivity between devices. If any action is required, the next screen will explain to the patient what they need to do.

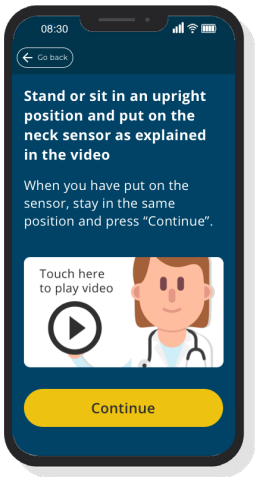


Once the app has confirmed the battery levels and sensor connections are adequate, the patient will be asked to watch a video, which explains how the study will work and what will happen.

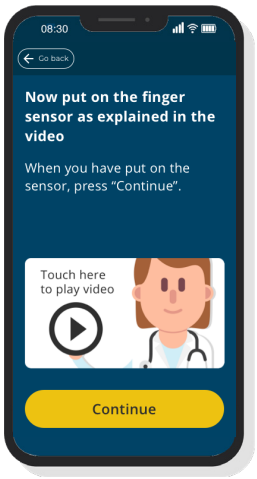
The app explains how to check that the sensors have a new, unpeeled adhesive. If the patient presses "Yes", the app continues to the next screen. If they press "No", a video explains how to replace the adhesive, which the patient must do before continuing.



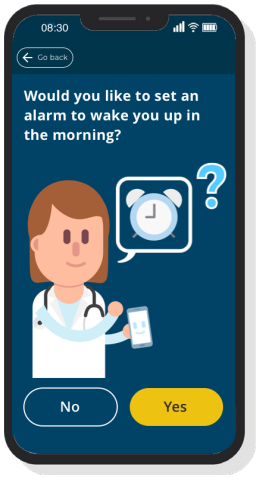
The patient will be asked to confirm they are about to go to sleep. If they press "Yes", they can continue. If they press "No", they will be asked to remove the finger sensor, then wait and return to the app when they are about to go to bed.



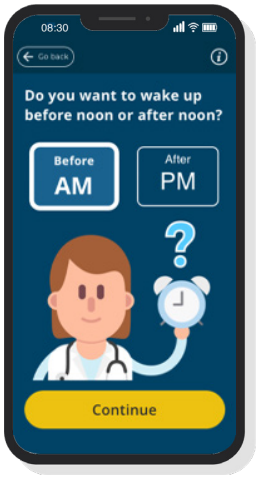
The patient should now put on the AcuPebble neck sensor, following the video instructions provided in the app. They can watch the video as many times as they need to.



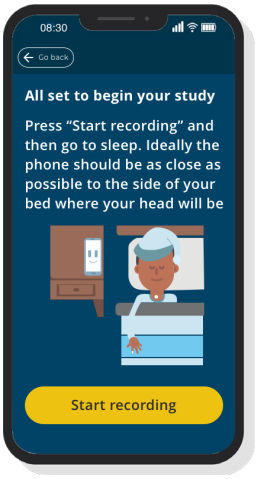
The patient will now be asked to put on the finger/forehead sensor, following the instructions in the mobile app. The app will check the battery level is sufficient to conduct a sleep test.



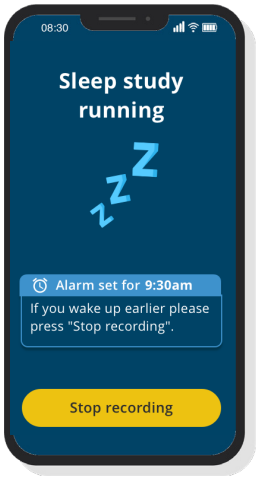
The app will next give the patient the option to set an alarm for the following morning. If they press "Yes", the app will take them through how to do this step by step. If they say "No", it will continue to the start of the study.



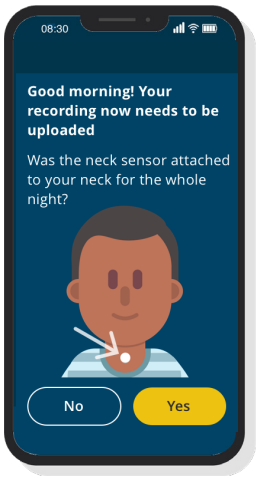
If the patient chose to set an alarm:
The app will display a series of screens allowing them to enter and confirm the time at which the alarm should go off.



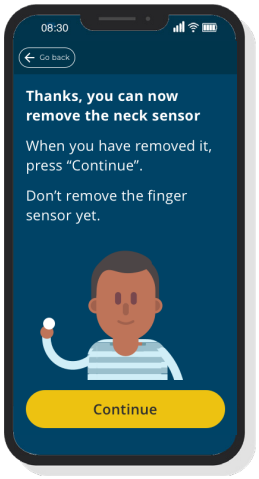
When they are ready, the patient can press "Start recording" and place the mobile phone next to the bed as instructed, then go to sleep as normal.



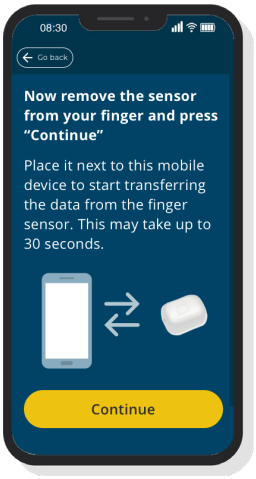
When the patient wakes up in the morning, they should stop the recording. If they set an alarm but wake up before it goes off, they can stop the recording earlier and the alarm will then be cancelled.



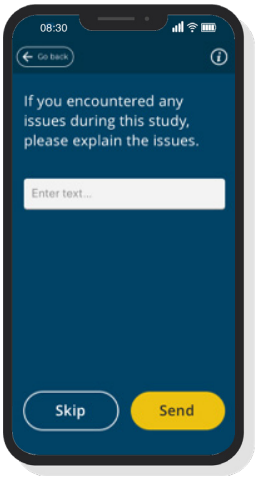
When they have stopped the recording, the patient must confirm if the AcuPebble sensor was still attached to their neck when they woke up. If they press "Yes", they can continue to the next screen. If they press "No", they may need to repeat the test the following night. The app will provide instructions if this is the case.



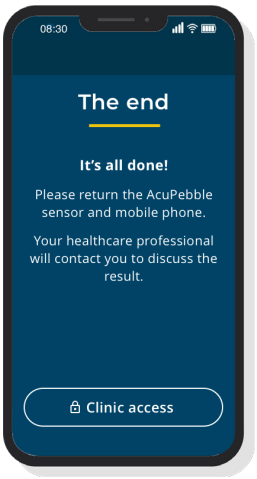
The patient can now remove the AcuPebble sensor from their neck.



The patient should next remove the oximetry sensor from their finger or forehead.



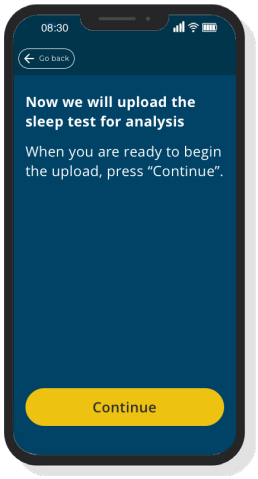
If the patient experienced any issues while conducting the study, or would like to make any comments, they can do so on this screen and then press "Send". If they have no feedback, they should press "Skip" to continue.
If the mobile device has an internet connection:
They will now need to upload the study by following the instructions in the app (see Appendix H).



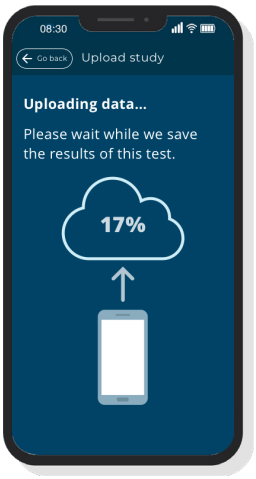
If the mobile device does not have an internet connection and is in hospital mode: The patient should return the sensor and mobile phone to their healthcare professional, so that the study can be uploaded for analysis (see Appendix H).

Appendix H: Upload a sleep study

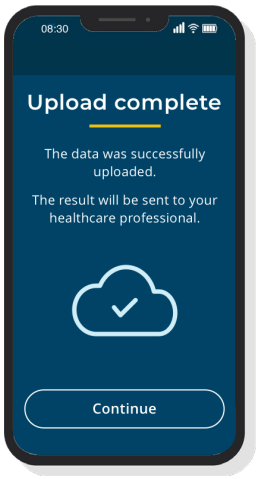
When the study has been conducted, it needs to be uploaded for analysis. This can be done by the patient if the mobile device they are using has an internet connection, or by a healthcare professional or other authorised representative if not.



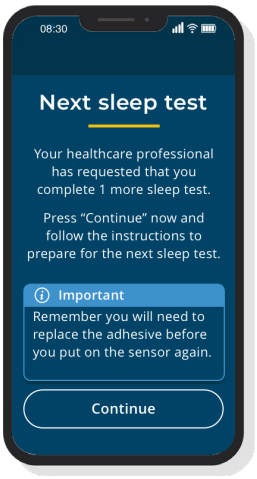
If the mobile device has an internet connection: the user can press "Continue" to start uploading the data. If the mobile device does not have an internet connection: the next screen will explain to the user what they need to do.



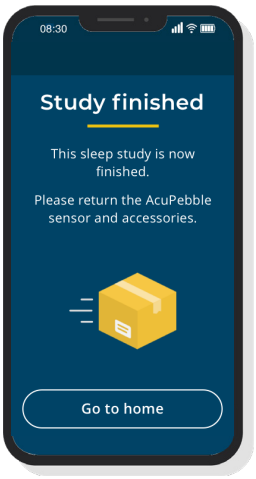
The data will be compressed and uploaded, and the app will display the progress on the screen.



The app will confirm when the upload is complete. When the user presses "Continue", the app will explain what they need to do next.



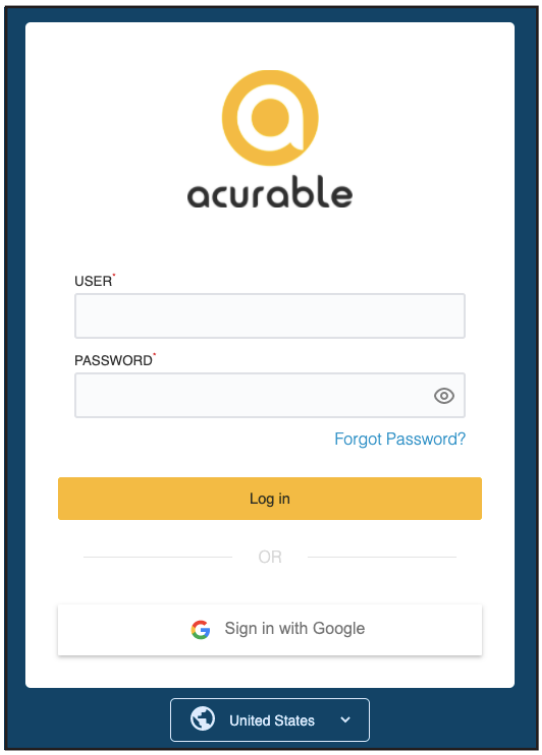
If the patient needs to complete further sleep tests: the app will remind them how many sleep tests they need to conduct to complete the study, and they can press "Continue" to start the next test.



If all tests have been uploaded: the app will confirm that the study is complete and the patient can return the sensor and accessories.

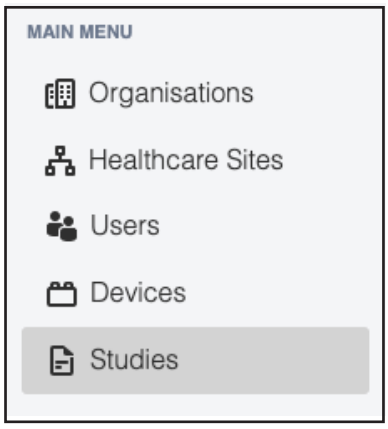
Appendix I: Accessing diagnostic data

1. Go to the web application at https://cloud.acurable.com.



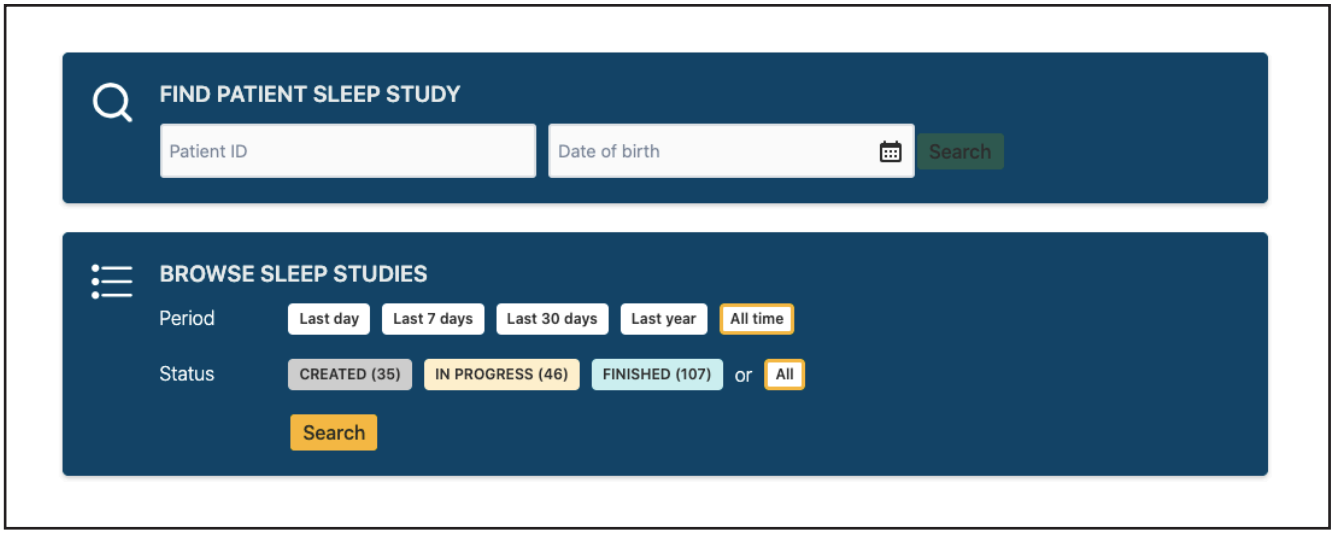
2. Enter your login details in the web application and press “Login”. If you’ve forgotten your password, you can reset it.

3. Select “Studies” in the main menu.

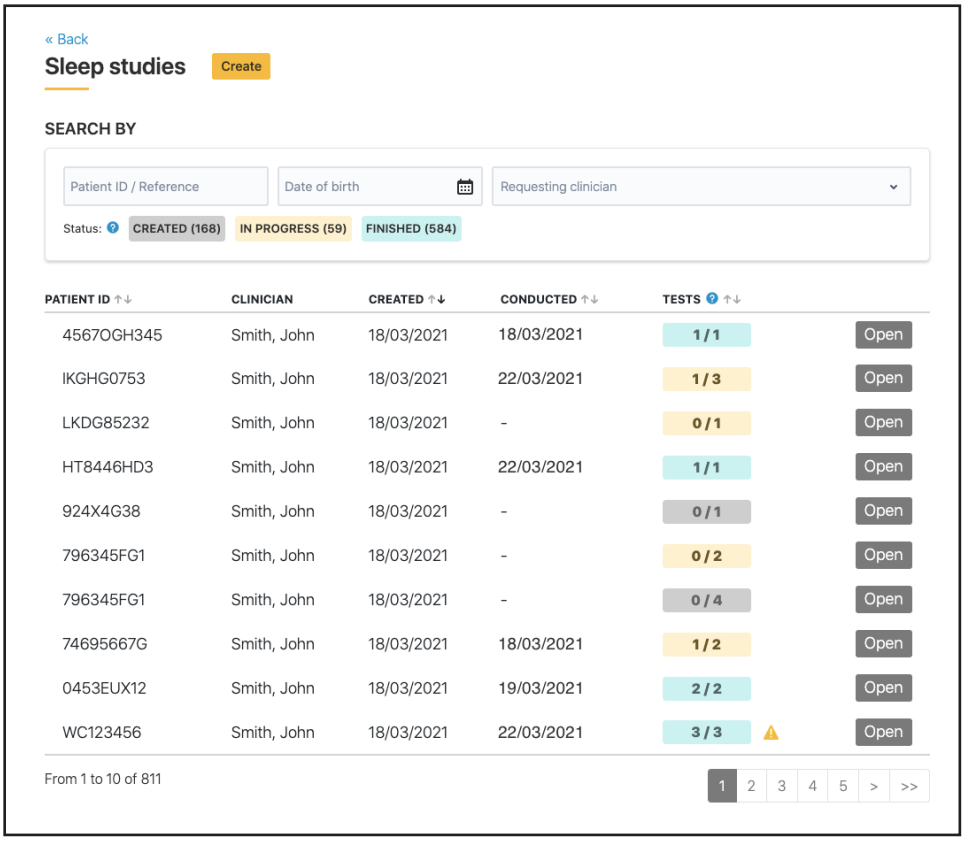


4. You can search for patient results using any of the following criteria:

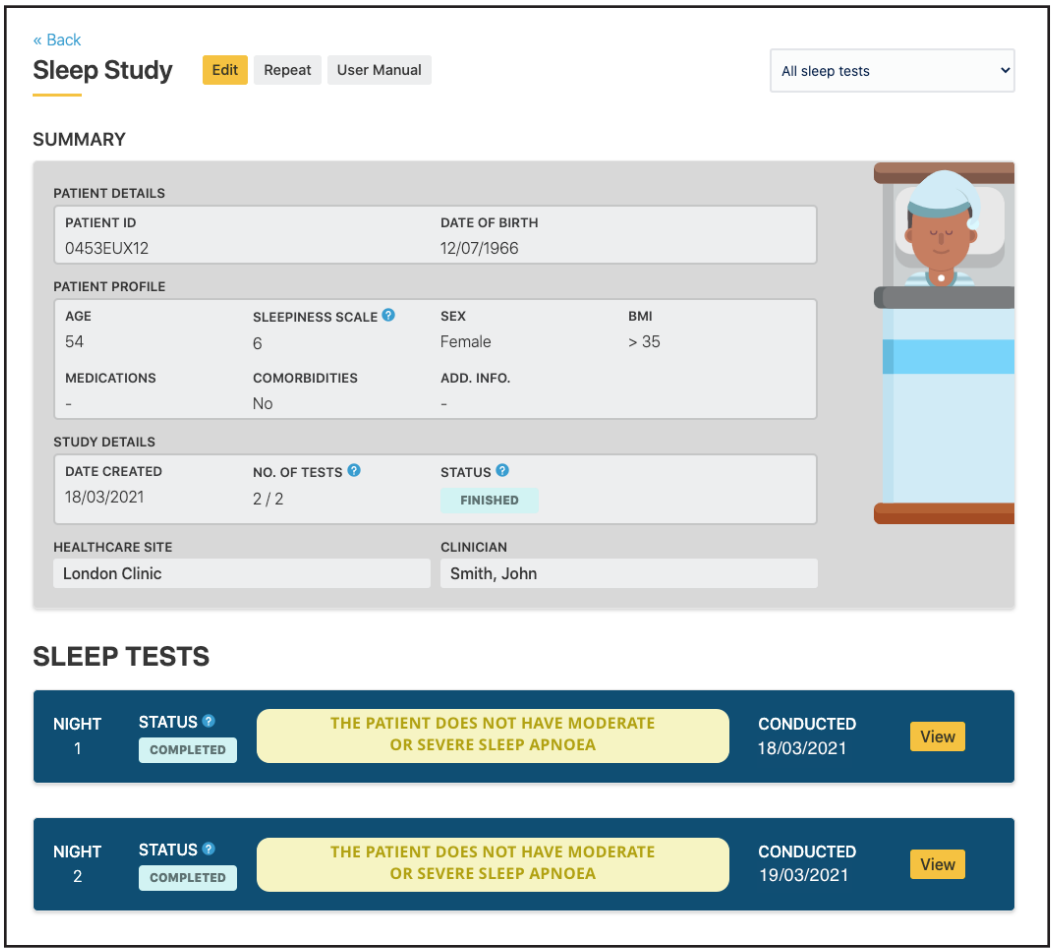
- Patient ID
- Date of birth
- Date
- Status



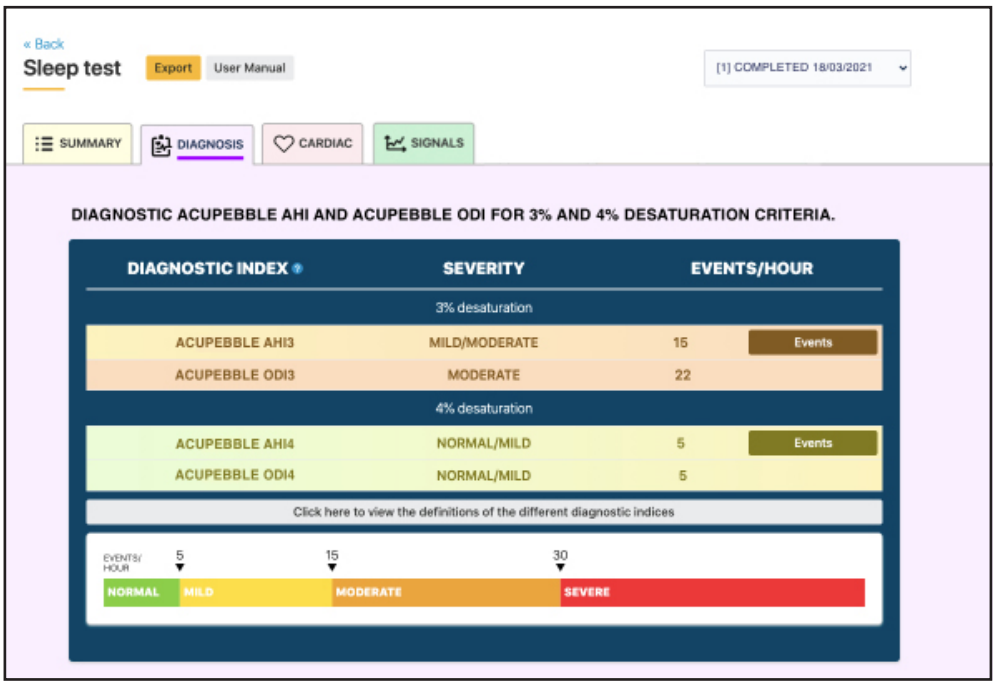
5. Click "Open" to select the study you need.

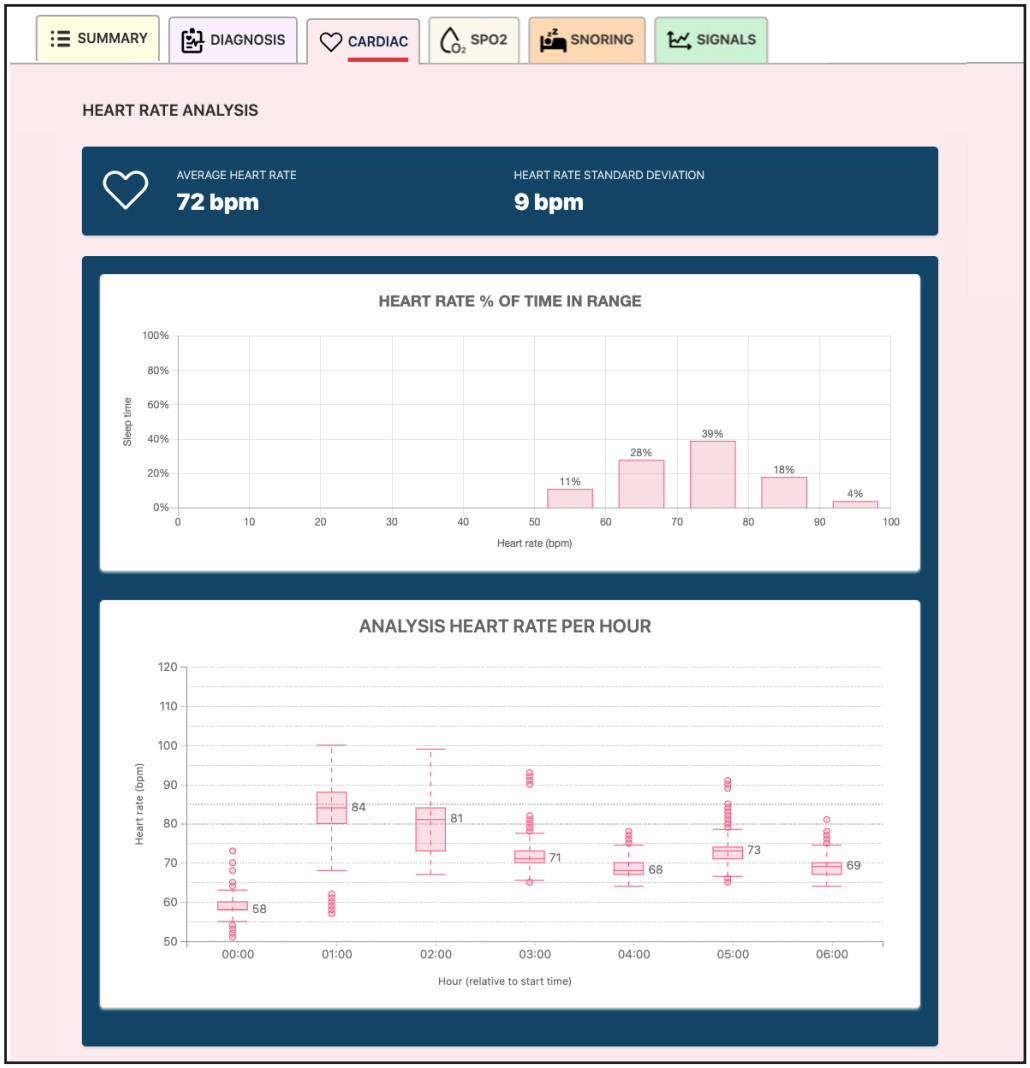


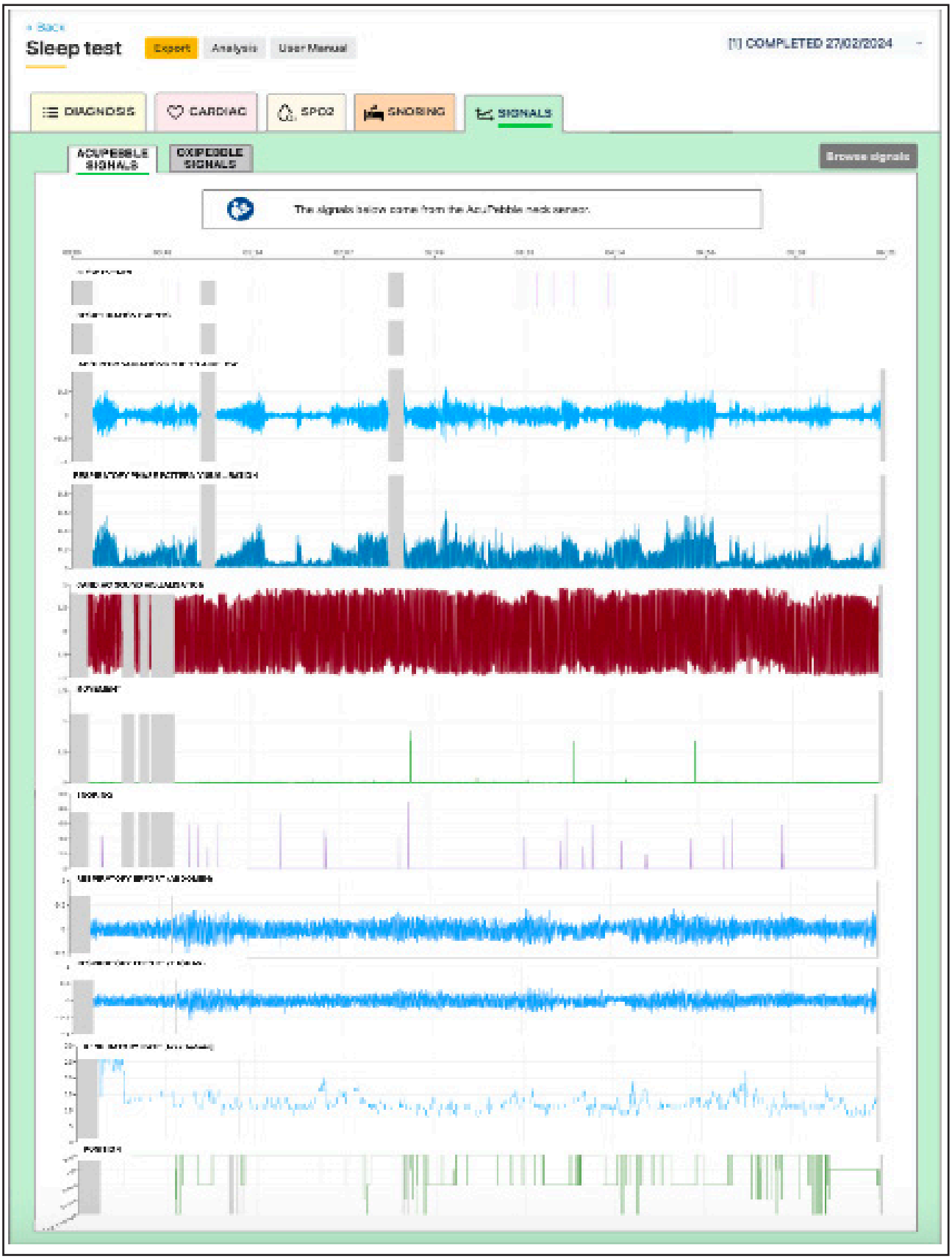
6. Once a study has been selected, a summary screen will appear which displays all the sleep tests within the study and their current status.



7. Once a study has been selected, a summary screen will appear presenting the results (refer to Section 20 for information on clinical validation of the results). You can click “Export” to download a summary of the results as a PDF. Additional reports and visualization of physiological channels are also available, which provide further detail about the patient’s sleep study. Access to some of these options will depend on the contractual agreement with Acurable. Examples of screens are shown below.







WEARABLE MEDICAL DEVICES